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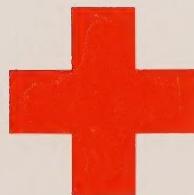
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FINAL SUBMISSION OF
THE CANADIAN RED CROSS SOCIETY
TO THE
COMMISSION OF INQUIRY ON THE
BLOOD SYSTEM IN CANADA

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The Canadian Red Cross Society

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COMMISSION OF INQUIRY ON THE BLOOD SYSTEM IN CANADA

THE CANADIAN RED CROSS SOCIETY SUBMISSIONS

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III. CRCS RESPONSE TO THE THREAT OF AIDS

A. AIDS: A Threat to the Balance

450. As was stated in a recent decision of the New Jersey Supreme Court:

In 1996, concerns about a diminished blood supply and public hysteria pale in the face of a blood recipient tragically infected with the AIDS virus. However, the recipients in the vigorous public debate in 1983 and 1984 about the utility [of core testing] did not have such a clear view of the future...⁶⁸²

451. To understand the decisions made by the CRCS throughout the 1980s to respond to the threat of AIDS in the blood supply, it is necessary to be cognizant of the delicate balance between supply and demand. Given the state of knowledge about AIDS from 1982 to 1985 and the perceived minimal risk of acquiring AIDS through blood transfusion, the CRCS had to be wary of operational changes which would significantly reduce collections, alienate donors, offend members of high-risk groups⁶⁸³, and panic either the public or recipients of blood or blood products. The perceived risks had to be weighed and balanced against the requirement to maintain an adequate and continuous supply for the 330,000 Canadians who required blood and blood products annually.

452. The CRCS faced the AIDS crisis at a time of continuous and chronic blood shortages. From 1982 to 1986, the CRCS experienced severe blood shortages in the Toronto, Montreal and Vancouver areas.⁶⁸⁴ In the summer and fall of 1984, the CRCS received letters

⁶⁸² *Snyder v. AABB* p. 22 (1995), 665A 2d 1107 at p. 22.

⁶⁸³ *Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies*, p. 40566.

⁶⁸⁴ *Evidence of Mr. George Weber, former Secretary General CRCS*, p. 40568.

Note that 65% of all collections come from these centres.

Evidence of Dr. Perrault, former National Director, BTS, pp. 29270-29271.

from Dr. Pinkerton of the Toronto Sunnybrook Hospital and Dr. Barkun of the Montreal General Hospital concerning the "dangerous clinical situations" caused by these blood shortages.⁶⁸⁵ A considerable number of elective surgeries had to be deferred. In 1984 in central Ontario, 9,000 units of blood were imported from other blood centres.⁶⁸⁶ In October 1984, Dr. Growe reported that shortage problems had been so acute in British Columbia, that there had been no surgery performed on hemophiliacs for the previous year and a half (except for two emergency procedures).⁶⁸⁷ The effect of these shortages was profound as Toronto, Vancouver, and Montreal centres combined accounted for some 65% of all collections done in Canada.⁶⁸⁸

453. Unlike the Americans, the CRCS could not maintain the level of collections by increasing the incentives to paid donors to compensate them for the inconvenience and embarrassment of more stringent donor screening practices. The CRCS kept abreast of evolving knowledge. It balanced the perceived risk of AIDS and the consequent stricter donor screening requirements against the fear of an inadequate blood supply. It strove to ensure that it was not casting the net too widely so as to eliminate those not at risk for AIDS.

454. Stricter donor screening requirements inevitably resulted in discouraging a greater number of donors. If requirements were set too high, regular, low-risk donors who had never transmitted disease were caught in the net and needed to be replaced often by new, first-time donors. New donors could be at higher risk for transmissible diseases and might not be screened out in the window period before developing antibodies. The risk to the blood supply increased with the non-specificity of a screening measure which eliminated donors not at risk and required

⁶⁸⁵ Ex. 629, Vol. 26, Tab 11 (October 22, 1984, Memo from National Director BTS to Secretary General).

⁶⁸⁶ Ex. 636, Vol. 33, Tab 31, p. 9 (Central Ontario Study);

Evidence of Dr. Perrault, former National Director BTS, p. 27078.

⁶⁸⁷ Ex. 758, Vol. 164, Tab 29 (Letter from Dr. Growe to Dr. Card, October 19, 1984).

⁶⁸⁸ *Evidence of Dr. Perrault, former National Director, BTS, pp. 29270-29271.*

a greater number of new donors.⁶⁸⁹ To recruit new donors to keep collections at the necessary level also required greater funding from an already cash-strapped BDR and a greater use of BDR personnel, who were often already working to capacity.⁶⁹⁰

455. As well, more extensive donor screening procedures to weed out those at high risk for AIDS increased donation time. There was a concern that this would discourage regular, low-risk donors from returning, particularly if the questions were more intrusive.⁶⁹¹ In 1983, the social mores did not permit intrusive or personal questions about sexual orientation and conduct where donors were volunteers.⁶⁹² The word "condom" was considered by some to be too sexually explicit to be included in public information about AIDS in 1983.⁶⁹³ The gay

⁶⁸⁹ While donor education by BDR personnel at the front end helped the blood supply in the long run to ensure that only desirable donors were recruited, there remained residual risk.

⁶⁹⁰ Evidence of Léandre Laflamme, Director of BDR, Eastern Quebec, p. 15331; Evidence of Linda Gauthier, Director of BDR, Western Quebec, p. 15300; Evidence of Dr. Guevin, former Medical Director Quebec Centre, p. 15922; Evidence of Dr. Huntsman, St. John's Centre Medical Director, p. 13852-53; Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, p. 40787; and Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30044-30045.

⁶⁹¹ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 463-466; and Evidence of Dr. Turner, Edmonton Centre Medical Director, pp. 7348-7350.

⁶⁹² Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8574-8576; Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9820-9821; and Evidence of Dr. Margaret Fast, former Assistant Provincial Epidemiologist, Manitoba, pp. 10423-10424.

⁶⁹³ Evidence of Dr. Johnstone, former Director of Division of Epidemiologist, Ministry of Health, B.C., pp. 4298-4306 and 4415; Evidence of William Mindell, CHS Member (Ontario Chapter), pp. 32359-32361; Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41794-41798;

community was not as politicized or vocal as today; accordingly, the average person knew very little about gay culture and behaviour. Many donors would have been offended by direct sexual questions, particularly about homosexual activity. The social climate was different in the early 1980s than it is today.

456. Concerns about discouraging or offending donors must also be considered in the climate of fear and hysteria surrounding AIDS from 1982 to approximately 1986. This should not be underestimated. There were reports of gay men being shunned by friends and family members and refused treatment by medical staff in hospitals due to a fear that AIDS could be transmitted by casual contact. Gay men were fired from their jobs and evicted from their homes.⁶⁹⁴

457. There was substantial misinformation about AIDS in the general public, which led many persons to refrain from blood donation because they believed that they could contract AIDS by *donating* blood.⁶⁹⁵ In July 1983, it was reported that AmCross experienced a drop in donations of 16% due to misinformation about AIDS.⁶⁹⁶ There was evidence that, even in

Evidence of Dr. McCarthy, AIDS Panel, pp. 9697-9700;

Evidence of Mr. Landry, CHS Panel (NB), pp. 11470-11471;

Evidence of Kirkwood, Deputy Minister of Health and Welfare, pp. 43926-43928; and

Evidence of Dr. Soskolne, Dr. Gilmore, NAC AIDS Panel, pp. 24916-24919.

⁶⁹⁴ Ex. 551, Vol. 125, Part II, Tab 3 (Article in *Time* entitled "The Real Epidemic: Fear and Despair", dated July 4, 1983).

⁶⁹⁵ *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 463-466;*

Evidence of Dr. Pinkerton, Director, Sunnybrook Hospital Blood Bank, p. 3803; and

Evidence of Dr. Jessamine, Chief of Field of Epidemiology Division, LCDC, pp. 41571-41572.

⁶⁹⁶ Ex. 551, Vol. 125, Part II, Tab 3 (July 4, 1983 Article in *Time* entitled "The Real Epidemic: Fear and Despair").

May 1985, 25-40% of donors held the belief that they were at risk for AIDS by donating blood.⁶⁹⁷ A survey conducted as late as 1994 on behalf of the Montreal Centre showed that 26% of persons believed that they could get AIDS by donating blood.⁶⁹⁸ A recent Gallup Poll indicates that this confusion still exists among some members of the public.⁶⁹⁹

458. The CRCS had to be vigilant and sensitive to the effect its response to AIDS would have on its volunteer donors. It was thought inappropriate to take action based on a possible but remote theory that would jeopardize the supply of blood to all those who needed it. Any action had to be predicated on a careful balance of all interests. Favourable public opinion is critical in an all-volunteer blood supply.⁷⁰⁰

459. The CRCS fears were not irrational. It has been shown that negative press can shake the confidence of donors and recipients alike:

I cannot prove it, sir, but I think there is no question that that is true. And when we met the other evening and I saw this news flashing, "Blood desperately needed in Toronto," really - you are having the same kinds of problems we are. And I think the adverse publicity, I think people don't trust us any more. They don't view us as doing good. And I think it has hurt us, yes...

...I think it is very serious because there was a conference - there was a blood forum in the United States looking at issues like public perceptions of blood banks and we had some specialists, professors of risk management and of public perceptions at a session that we held about a month and a half ago and Professor Chess got up and talked about lack of trust in the American blood supply, and I suspect in Canada as well, but that is pure speculation. And we asked her at the close of her presentation: "How do you get the trust back?" And she said,

⁶⁹⁷ Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40681-40682; and

Ex. 635, CRC Vol. 32, Tab 13 (May 15, 1985 Memo from the Secretary General to file re: Media Coverage of AIDS).

⁶⁹⁸ Evidence of Dr. Decary, Montreal Centre Medical Director, pp. 16047-16051.

⁶⁹⁹ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 463-466.

⁷⁰⁰ Evidence of Dr. Perrault, former National Director BTS, pp. 27657-27660.

"You can't," which was sobering. So we have a big up hill fight in the United States and I suspect in Canada to try to regain public trust.⁷⁰¹

⁷⁰¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22299-22300.

B. **DONOR SCREENING (1982 - 1985)**

1) **CRCS Donor Screening Practices Were Based on Risk Assessment**

460. Starting in the mid-1970's, each donor who attended a CRCS blood donor clinic was provided with a health questionnaire which was designed to ensure the health of the donor and to minimize the risks to the recipient. Among the questions posed on this pre-AIDS Donor Questionnaire were:

- Do you now or have you ever had:
 - hepatitis?
 - malaria?
 - any other chronic health problem?
- In the past three years:
 - have you been outside Continental North America?
 - did you take medication to prevent malaria?
- In the past six months have you had:
 - any serious illness or have you required physician or hospital care?
 - transfusion of blood products, tattoo, ear piercing?
 - contact with infectious hepatitis?
- Do you now have:
 - sore throat, flu, skin problems?
- Are you presently taking any medications or injections?
- Within the past 24 hours:
 - have you taken aspirin or anything for headache, cough, cold, arthritis or stomach upset?⁷⁰²

461. Donors were told to read the Donor Questionnaire. If they answered in the affirmative to any one of the questions, they were directed to a clinic nurse who would discuss with them their eligibility to make the donation. If the nurse could not determine whether the donor was eligible, she would consult the National Donor Selection Criteria Manual. This manual listed various medical conditions and medications and provided information as to whether

⁷⁰² Ex. 610, CRC Vol. 7, Tab 5 (CRCS BTS Donor Questionnaire).

the donor ought to be deferred and, if so, specified the length of time. Some local centres had their own supplementary working guides to assist nurses in answering questions frequently asked by donors in their centres. These were permitted so long as they were consistent with National guidelines.⁷⁰³

462. All donors were seen by nursing staff when they underwent the phlebotomy procedure, regardless of whether they directed themselves to a nurse as a result of their answers to the Donor Questionnaire. The nurses would often ask the donors further questions about their health such as, "are you well?". Also, nurses were always entitled to use their clinical judgment and if a person did not look well, the nurse would either defer the donor or accept the donation and flag it for discard.⁷⁰⁴

463. As will be discussed in this section, stricter donor screening measures, and in particular the policy of voluntary self-exclusion, were the CRCS's first line of defence in 1983 against the possibility that AIDS could be linked to a new infectious agent in the blood supply. The CRCS recognized that prudence required action before there was scientific certainty as to the mode of transmission of AIDS in order to protect the blood supply⁷⁰⁵:

Now, I had drawn the distinction, sir, in my previous evidence, given, I believe, in response to Ms Edwardh's early questions between scientific conviction and action that could and should prudently be taken at a given time about any given problem. And that was with specific reference to early precautions about AIDS. And that is precisely the position that I took, that where there were things that should prudently be done, whether or not one was convinced by the scientific

⁷⁰³ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27135-27141.

⁷⁰⁴ Evidence of Dr. Perrault, former National Director BTS, p. 27145;
Evidence of Dr. Buskard, Clinical Professor of Medicine, University of British Columbia, p. 5476;
Evidence of Dr. Davey, former Assistant National Director BTS, p. 27565; and
Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, p. 9850.

⁷⁰⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27306, 27386-27387.

evidence, action was taken to do them. And I believe that that stands up in the record.⁷⁰⁶

464. The actions taken by the CRCS during the 1980's resulting in stricter donor screening measures balanced the actual knowledge of the disease against the need to maintain an adequate blood supply:

...we are talking about circumstances of early 1983, one acted to try to exclude high risk individuals, but balanced -- the benefit of that which at the time didn't -- you know would seem relatively small in terms of the risk of AIDS, against the hazard of doing so to blood supply, to operation of blood services, and the community disadvantages of attempting it. So one acted prudently on what was then an assessment of a fairly low risk.⁷⁰⁷

465. The implementation of new donor screening measures must be examined in the context of the appreciation of risk as it evolved. Given the unrecognized long latency period of the virus, and absent a test for the agent causing AIDS, it was not possible to measure the efficacy of new donor screening measures. The fact that there were no TAA cases in Canada until 1985 led to the conclusion that the existing system was working:

I think one has to go back to the day, as one can 11 years ago in a fog bank, and remember that we knew nothing about the transmissibility of this disease for certain. To, therefore, implement any number of changes, when one could not test the hypothesis that it was indeed improving recipient outcome and indeed would be very costly to the system in terms of donor deferral, in terms of a decrease in donor blood in general, that you really must take into consideration there could be no way of proving that a measure you were taking was working. Therefore, how do you document that you should indeed be doing something or not.

Indeed, if you did in 1983 have a zero transmission of AIDS by blood documented at that time, how do you test any intervention for a change in outcome?...

It wasn't a money issue. It was an issue of we had a system in place of a blood program that was indeed meeting the needs of the recipients and the envy of the world in fact, as the Canadian blood system.

⁷⁰⁶ *Ibid*, p. 29302.

⁷⁰⁷ *Ibid*, pp. 30759-30760.

To interfere with the smooth flowing of a blood program that was meeting the needs of the surgical base in particular, the everyday lives of our recipients, without having a solid justification, would be a difficult measure, not an impossible one. You do not always in science have to have a testable hypothesis, but you will not get funded any hypothesis that is not testable.⁷⁰⁸

466. From 1982 to 1984, two risk assessments had to be counterbalanced:

...one was assessment of what the risk of AIDS associated with transfusion appeared to be at the time, which we could only base, at least in '83 and '84, on the cases that had actually occurred. And the other, the assessment of risks incurred in over-reacting, as it were, to the problem in terms of effects on the blood supply and also the impact of information and precautionary steps on people on whom they impacted, say as blood donors deferred and left with an impression that they individually might be at risk. So we put these two assessments together. And they both informed the action actually taken.

Now, the risk to the blood supply for example arose in terms of any type of violent or widespread public reaction in terms of -- to measures taken by people. For example: alleging discrimination or discriminatory practise and that steps taken were unreasonable.⁷⁰⁹

467. Such assessment was difficult in a vacuum of scientific knowledge, especially when there were also many conflicting interests at play.⁷¹⁰ These interests were aired at the January 4, 1983 CDC meeting:

...what was going on were countervailing interests, trying to solve a problem. And let's just give a simple example of how they are countervailing interests.

The gay groups did not want to have their lifestyle become a subject of inquiry, in other words, did not want to be asked questions about lifestyle. They wanted a surrogate test because, test everybody and it is equal and it is fair and there are no civil rights involved. If you ask us, as individuals, our lifestyle, then you have somehow set us aside and stigmatized us.

⁷⁰⁸ Evidence of Dr. Bowen, former Calgary Centre Medical Director, pp. 7718-7719.

⁷⁰⁹ Ex. 743, Tab 34 (*Excerpt from Transfusion Today*, No. 21, entitled "Risk Assessment and the Use of Factor VIII Concentrates during 1983-1985", by Dr. Hughes-Jones, December 21, 1994); and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30753-30758, 30881.

⁷¹⁰ Ex. 554, Vol. 128, Part I, Tab 2 (*Minutes of CDC Work Group to Formulate Recommendations for Prevention of AIDS*, dated January 4, 1983).

There were people that were worried about costs, that: "Oh, my God. If we do this, we are going to have so many dollars are going to be expended through a variety of things." There were people who didn't care about costs. There were people who wanted a purer scientific approach. "This has not been proven yet, and until it is proven, we shouldn't scare a lot of people." And there are other people that say, "Look, we have got enough data. We had better do something and if we are wrong, we can always back off and say, 'Okay, it isn't transmitted by blood.'"

So in the room, you had this, at it has been described and again this is all hearsay, but it has been described many, many times by many, many different people. There was a lot of tension in the room. There were a lot of agendas. And so when it says that: "...Consensus was reached..." it was a reluctant consensus by a lot of people. I just thought I would try to paint a landscape.⁷¹¹

468. The CRCS and the other players in the Canadian blood system believed that the donor screening measures that were implemented were appropriate and effective at the time.⁷¹² There were no reported cases of transfusion-associated AIDS in Canada until March 1985, at which time LCDC reported one infant case.⁷¹³ Until May 1985, there were only two cases of

⁷¹¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22370-22371.

⁷¹² Evidence of Michel Chretien, former Chair of Royal Society of Canada Steering Committee, pp. 49023-49025;

Evidence of Dr. Sullivan, Medical Director of Employee Health, Nova Scotia, pp. 12725-12726;

Evidence of Dr. Johnstone, former Director of the Division of Epidemiologist, Ministry of Health, B.C., pp. 4480, 4488-4490, and 4499-4500;

Evidence of Dr. Jessamine, Chief of Field Epidemiology Division, LCDC, p. 41526;

Evidence of Dr. Clayton, Director General, LCDC, pp. 41620-41622, pp. 41920-41922;

Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 21420-21421;

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27593, 30879-30881;

Evidence of Janet Jones, member of Board of Governors, pp. 40356-40358;

Ex. 697, Tab 30 (Article in the Montreal Gazette, dated February 19, 1985 per Dr. Gilmore); and

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9777-9778.

⁷¹³ Ex. 1001, Vol. 247, Tab 21 (CDWR dated March 1985);

Ex. 116 (Current Status of AIDS Related to Blood Transfusion and Blood Products by Noel Buskard, dated March 6, 1985); and

AIDS in Canada attributed to the administration of blood products. In May 1985 the first two cases of TAA in adults were reported.⁷¹⁴ It was only after the implementation of HIV antibody testing that data became available demonstrating that donor screening in Canada, and elsewhere, had not been as effective as everyone had believed⁷¹⁵:

...What we thought, and we had data -- there was some not compelling data, but we had some studies in Atlanta that Dr. Grinden (phonetic) published, and we had some data from Philadelphia that Dr. Dolkie (phonetic) published, suggesting that all the indications were that the age group of men that were actively homosexual, that age group had dropped dramatically in its donations. The amount of hepatitis B, as we know which runs along with HIV infection, that was dramatically dropping. And so we had a lot of evidence to suggest that what the gay leadership had told us that in fact, gays were no longer donating blood.

And then as we started testing, we started accumulating the data, particularly in the fall of 1985, we have all these positive tests, and we literally looked at these data and said, "Who are these people?" ...a study was set up between CDC and the Atlanta Red Cross, and in interviewing these people and counselling them about their positive test results, it became evident that most of them were gay, the vast majority, 90 per cent of them were gay men, that for whatever reason, whether it is denial, whether it is test seeking which we will talk about a little bit, I guess, towards the end, for whatever reason, these people were continuing to donate blood. And it was of deep concern to us.

So as these data emerged late in '85 and early '86, a couple of events occurred: the data was becoming uncovered in Atlanta; and other studies were undertaken; blood centres started to weigh in as they counselled donors, yes, gays were in fact giving, albeit at reduced numbers, they were still there; and secondly, at FDA we started to get funding to do interventions, improve the way we asked the questions of donors. Clearly, our screening that we had believed was being affected was not as effective as we had hoped or believed, and so additional strategies had to be undertaken.⁷¹⁶

Ex. 1002, Vol. 248, Tab 9 (HPB Briefing Information on AIDS, dated April 12, 1985).

⁷¹⁴ Ex. 1002, Vol. 248, Tab 44 (CRCS Press Release, dated May 10, 1985 and Memorandum to the Minister from David Kirkwood, dated May 13, 1985).

⁷¹⁵ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22544-22546.

⁷¹⁶ Ibid, pp. 22419-22423.

469. In 1983 the incidence of AIDS in Canada was only approximately one-quarter of that in the United States and has remained as such⁷¹⁷. Even allowing for this variable and adjusting for population, the United States currently has about 4 times the rate of TAA but only 1.8 times the rate of cases of AIDS due to blood components. This latter figure can be explained by the lack of Canadian self-sufficiency in plasma and the heavy reliance of Canadian hemophiliacs upon American source plasma.⁷¹⁸

2) Donor Screening Standards

470. The CRCS collects blood from a few fixed donor clinic sites and many more mobile clinic sites in order to collect sufficient blood to serve local hospitals' needs. It has relied heavily upon the generosity of others to provide sites suitable for mobile clinics, such as

⁷¹⁷ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27937-27940;

Ex. 551, Vol. 125, Part II, Tab 63, p. 233 (MMWR, dated December 9, 1983);

Ex. 552, Vol. 126, Tab 9, p. 48 (MMWR, dated January 6, 1984);

Ex. 1038 (Information Letter - Health Protection Branch re: Toxic Shock Syndrome, dated February 20, 1981);

Ex. 1002, Vol. 248, Tab 49 (Memo to Provincial Deputy Ministers from David Kirkwood, undated); and

Ex. 1002, Vol. 248, Tab 36 (Minutes from NAC AIDS Meeting, dated May 15, 1985, p. 14);

Ex. 1301 (Dr. Davey Expert Report in CRCS at Walker/Osborne.)

Ex. X1279 ("An International Comparison of Transfusion-Associated HIV Infection: How Well Did Canada Do?" by Dr. Remis and Dr. Vandal).

⁷¹⁸ Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey); and

Ex. X1278 ("An International Comparison of the Incidence of AIDS Associated with Blood and Blood Products" Abstract of Poster Presentation by Dr. Davey from the annual meeting of the Canadian Society for Transfusion Medicine, May 24-26, 1996);

Ex. 1028, Vol. 286, Tab 7 (Comparative Analysis of AIDS Incidence, Total and Associated with Clotting Factors and Transfusion, cumulative to March 1995 for selected countries in North America, Europe and Oceania, dated August 11, 1995, by Dr. Remis).

church basements, schools, legion halls or factories.⁷¹⁹ Before the advent of AIDS, the CRCS system was designed to process donors quickly on a mass basis.⁷²⁰

471. As will be discussed in this section, AIDS brought a new series of challenges in screening blood donors. The physical site of the clinic had to allow for greater privacy to donors, who were required to answer highly personal questions.⁷²¹ The health screening process took longer and led to longer donor line-ups and more impatient donors.⁷²² The federal authorities assumed greater regulatory control over all aspects of the blood collection process and Regulations and Standard Operating Procedures were introduced.⁷²³ Previously, National office disseminated a National policy, which could be expanded upon or implemented in a unique manner, so long as it was consistent with National policy.⁷²⁴ For the first time, all aspects of the blood collection process were licensed and thereby standardized.⁷²⁵

472. In the early 1980's, several Medical Directors across the country instituted local variations in donor screening as they thought appropriate considering their donor base and clinic environments. Medical Directors could speak with Drs. Davey, Perrault and Derrick to make their views known about national donor screening and other issues.⁷²⁶ Response from National

⁷¹⁹ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 410-412.

⁷²⁰ Evidence of Dr. Davey, former Assistant National Director BTS, p. 28028.

⁷²¹ Ibid, p. 28028.

⁷²² Evidence of Dr. Turner, Edmonton Centre Medical Director, pp. 7348-7350.

⁷²³ Evidence of Dr. Furesz, BoB Panel, pp. 42796-42798.

⁷²⁴ Evidence of Dr. Buskard, Clinical Professor of Medicine, UBC, pp. 5756-5758; and
Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27135-27141.

⁷²⁵ Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40466-40467; and

Evidence of Janet Jones, Board of Governors Panel, pp. 40223-40225.

⁷²⁶ Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 9015-9017.

Office to comments, suggestions, and requests was rapid.⁷²⁷ Senior National Office staff were aware of local variations to donor screening and did not advise centres against implementing additional initiatives, so long as National procedures were also followed.⁷²⁸ For example, some centres provided donors with in-house pamphlets and, later, AIDS educational sheets, NACAIDS pamphlets, as well as the National CRCS pamphlet.⁷²⁹ Other centres displayed a large poster at the blood clinic site to provide further information about AIDS.⁷³⁰ The National Office considered this to be an optional local initiative.⁷³¹

⁷²⁷ Evidence of Dr. Bowen, *Calgary Centre Medical Director*, pp. 8104-8105.

⁷²⁸ Evidence of Dr. Davey, *former Assistant National Director BTS*, pp. 28500-28501.

⁷²⁹ Evidence of Dr. Buskard, *former Vancouver Centre Medical Director*, pp. 5757-5758;

Ex. 640, CRC Vol. 37, Tab 24 (BC Pamphlet entitled AIDS, Information for Blood Donors, AIDS Update, November 1985);

Ex. 111, Vol. 47, Tab 79, p. 53374 (*Vancouver Centre Health Assessment/Donor Questionnaire*, dated March 19, 1987);

Evidence of Dr. Bowen, *Calgary Centre Medical Director*, pp. 7922, 28022-28026;

Ex. 620, CRC Vol. 17, Tab 19 (*Memo from Dr. Bowen to Dr. Davey*, dated July 26, 1983);

Ex. 165, Vol. 62, Tabs 27-29 (Supplementary laminated handouts to donors, dated approximately 1985 and used at *Calgary Centre*);

Evidence of Dr. Turc, *former Edmonton Centre Medical Director*, pp. 7570-7572; and

Ex. 128, Vol. 53, Tab 9 (*Pamphlet in use starting in approximately March 1985 in Edmonton and July 1985 in Calgary*).

⁷³⁰ Ex. 177 (*Photograph of poster in use at Edmonton Centre in March of 1985*);

Ex. 164, Vol. 60, Tab 22 (*Letter from Dr. Turc to Dr. Perrault*, dated May 16, 1985, enclosing photograph of *Edmonton poster*);

Ex. 626, CRC Vol. 23, Tab 33, p. 12178 (*Hamilton Criteria Board in use before June 1984*);

Evidence of Dr. Bowen, *Calgary Centre Medical Director*, pp. 7937-7942;

Evidence of Dr. Turc, *former Edmonton Centre Medical Director*, pp. 7396-7398; and

Evidence of Dr. Davey, *former Assistant National Director BTS*, pp. 28501-28502.

⁷³¹ Ex. 636, CRC Vol. 33, Tab 4 (*Minutes of Donor Selection Criteria Working Group Meeting*, dated June 10, 1985).

a) High-Risk Groups for AIDS

473. In January 1983, the U.S. commercial plasma industry, as opposed to the volunteer sector, advocated direct questioning of donors about their sexual orientation or Haitian origin. These steps were viewed by the volunteer donor industry (including the CRCS), as, not only unnecessary but inappropriate, given the appreciation of the risk of AIDS and the need to maintain a sufficient blood supply in the face of recurring shortages.⁷³² The gay community was greatly concerned about stigmatization and was very vocal.⁷³³

474. During this time, the CRCS considered its donor screening practices in relation to AIDS and balanced the perceived risk of AIDS against the fall-out which could occur if it over-reacted. Notwithstanding that the incidence of AIDS was a small fraction of that in the U.S., and the fact that there were no reports of AIDS in hemophiliacs or transfusion recipients in Canada, the CRCS issued its press release on March 10, 1983 (promptly after the March 4, 1983 HHS announcement).⁷³⁴ This press release defined high-risk groups for AIDS and requested that those at high risk temporarily refrain from donating blood until there was more information about AIDS. The definition of high-risk groups was based on epidemiological data and included "sexually active homosexual and bisexual men with multiple partners" and "recent

⁷³² Ex. 616, Vol. 13, Tab 12, paragraphs 6, 12, 13 (*Trip Report from Dr. Derrick to attend the NHF/Industry Meeting on AIDS, dated January 14, 1983*); and

Ibid., Tab 18, paragraphs 18-26 (*Minutes of Immunology/Virology Working Group Meeting, dated January 21, 1983*).

⁷³³ Ex. 554, Vol. 128, Part I, Tab 12 (*News from the NGTF, dated January 10, 1983*); and
Evidence of Dr. Hammond, Manitoba Public Health, pp. 10411-10413.

⁷³⁴ Ex. 615, CRCS Vol. 12, Tab 29 (*Information Letter No. 4, AIDS*);
Ex. 554, Vol. 128, Part I, Tab 54 (*HHS News Release, dated March 4, 1983*);
Ex. 616, CRC Vol. 13, Tab 43 (*AmCross News Release, dated March 4, 1983*); and
Ex. 550, Vol. 125, Part I, Tab 27 (*MMWR, dated March 4, 1983*).

Haitian immigrants".⁷³⁵ This definition was recommended by the Council of Europe and also followed in Australia, Belgium, France, Germany, Ireland, Holland and the United Kingdom.⁷³⁶ (A full discussion of the March 10, 1983 press release and subsequent measures is discussed later in this section.)

475. There was an immediate hostile reaction to the press release by the gay and Haitian communities, who made vocal cries of discrimination by the CRCS. Members of the gay community voiced concern about further stigmatization of their community, which had already experienced marginalization and discrimination. The Haitian community was outraged that it should be associated with such a disease in the absence of scientific data to explain why.⁷³⁷ The CRCS was concerned that gay men would make good their threats and picket blood donor clinics, which could have had a devastating effect on the blood supply.⁷³⁸

⁷³⁵ Ex. 617, CRC Vol. 14, Tab 3 (CRCS Press Release, dated March 10, 1983).

⁷³⁶ Ex. 715, Vol. 155 (International Overview of Donor Screening Measures introduced in 1983).

⁷³⁷ Ex. 659, CRC Vol. 56 (Newspaper Articles);

Ex. 1050 (Additional Media Documents on Voluntary Self-Exclusion not contained in Volume 56 of the Commission Productions);

Ex. 618, CRC Vol. 15, Tab 28 (Letter from Francine Fournier Quebec Human Rights Commission to Keith Cardiff, dated April 29, 1983);

Ex. 618, CRC Vol. 15, Tab 34 (Letter from H. Tellier to Francine Fournier, dated May 11, 1983);

Ex. 619, CRC Vol. 16, Tab 13 (Memo from Dr. Derrick to Dr. Perrault, dated June 2, 1983 re: Ontario Human Rights Commission); and

Ex. 623, CRC Vol. 20, Tab 21 (Letter from R.G.L. Fairweather, Canadian Human Rights Commission to George Weber, dated December 16, 1983).

⁷³⁸ Evidence of Ed Jackson, member of AIDS Panel, p. 23675; and

Evidence of Dr. Perrault, former National Director BTS, pp. 27555-27557.

476. The CRCS National Office, therefore, planned to directly approach members of high-risk groups to request that they temporarily refrain from blood donation.⁷³⁹ Meetings were necessary to diffuse the situation. Prior to its press release, on March 8, 1983, Dr. Derrick contacted Ed Jackson, Editor of the *Body Politic* and a gay community advocate, who agreed to provide Dr. Derrick with the names of representatives of gay communities across the country so that Medical Directors could make direct contact with local representatives.⁷⁴⁰

477. On April 8, 1983, Dr. Derrick and Eva Bart met with members of the Toronto gay community.⁷⁴¹ At that meeting, Dr. Derrick advised that all Medical Directors had agreed to make contact with representatives of high-risk groups in their areas to explain the policy of voluntary self-exclusion. Mr. Jackson, again, agreed to provide a list of local contacts. The meeting concluded with a consensus that a cooperative effort between the CRCS and the gay community was required. Dr. Derrick was well regarded by Ed Jackson (who testified before the Commission of Inquiry as a member of the AIDS panel), as a pleasant man with a sincere concern about the impact that the new donor screening measures would have upon the gay community.⁷⁴²

478. The minutes of the April 8, 1983 meeting between CRCS National office staff and members of the gay community were forwarded to all Medical Directors by Dr. Derrick under cover of a memo dated April 28, 1985. Dr. Derrick anticipated that Mr. Jackson would send the list of contact names in early May, after which Dr. Derrick would forward this information

⁷³⁹ Ex. 618, CRC Vol. 15, Tab 25 (*Memo from Dr. Derrick to all Medical Directors and Members of the CRC BTS Ad Hoc Working Group on AIDS, dated April 28, 1983*).

⁷⁴⁰ Ex. 616, CRCS Vol. 13, Tab 45 (*Memo from Dr. Derrick to Dr. Davey, dated March 8, 1983 re: AIDS and Donor Screening*).

⁷⁴¹ Ex. 618, CRC Vol. 15, Tab 10 (*Summary of Proceedings of a Meeting concerning Informational Exchange on AIDS between representatives of the Canadian Red Cross and Toronto Homosexual Groups, dated April 8, 1983*).

⁷⁴² *Evidence of Ed Jackson, member of AIDS Panel, pp. 23668-23671 and 23690.*

to Medical Directors to enable local contact.⁷⁴³ Dr. Derrick did not receive the information from Mr. Jackson until July 14, 1983. (It did not provide contact names for Regina, Toronto, Sudbury, Quebec, Montreal, St. John's or Saint John.⁷⁴⁴) That very day, Dr. Derrick forwarded this information and a magazine article listing gay support groups across the country to all Medical Directors.⁷⁴⁵ This letter was intended to assist those Medical Directors who had thus far been unsuccessful in their attempts to contact local members of the gay community and to explain the reasons why the CRCS was asking members of high-risk groups to self-defer from donation. Most Medical Directors were successful, as described below:

- **St. John's** - Dr. Huntsman made first contact with six representatives of the Gay Association in Newfoundland (GAIN) on March 21, 1983 at the St. John's Centre. At that time, he believed that this group represented all gay men in the province. An agreement was reached that members of the gay community would co-operate in disseminating the message that gay men were not to donate blood and would refrain from donating, so long as there were no discriminatory practices (i.e. mention of gay or bisexual donors) in the clinic.⁷⁴⁶ Consistent with that agreement, when the first pamphlet came out in May 1984, Dr. Huntsman wrote to

⁷⁴³ Ex. 618, CRC Vol. 15, Tab 25 (*Memo from Dr. Derrick to all Centre Medical Directors and Member of the CRC BTS Ad Hoc Working Group, dated April 28, 1983*).

⁷⁴⁴ Ex. 620, CRC Vol. 17, Tab 1, (*Letter from Ed Jackson to Dr. Derrick, dated July 12, 1983*).

⁷⁴⁵ Ibid, Tab 3 (*Memos from Dr. Derrick to Drs. Huntsman, MacKay, Gorelick, Wrobel, Barr, Schroeder, Turc and Bowen, dated July 14, 1983*)

A review of the various centre files some ten years later did not disclose this document in all centre files, however it is logical to presume that all Medical Directors received this memo.

⁷⁴⁶ Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13899-13903;

Ex. 332, Vol. 96, Part I, p. 23 (Minutes of Medical Advisory Committee Meeting, dated March 7, 1983); and

Ibid, p. 26 (Letter from Dr. Huntsman to Deputy Minister, dated March 28, 1983).

GAIN to advise its members that literature about high-risk groups would be distributed at the clinic.⁷⁴⁷

- **Edmonton** - Although his memory was unclear, Dr. Turner testified that he believes that after his Centre received the July 14, 1983 memo from Dr. Derrick, he approached the Gay Alliance Towards Equality (GATE) during the summer of 1983 and convened a meeting at a local theatre to explain the rationale behind the CRCS donor screening criteria. He recalled that the gay community was co-operative and that the information he conveyed was well received. Note that Dr. Turner's evidence and the subsequent evidence from Michael Phair at GATE is unclear as to a specific date and location. Nonetheless, Dr. Turc stated that Dr. Turner and Mr. Phair knew each other from 1983 activities.⁷⁴⁸
- **Calgary** - In the period of July 1983, Dr. Bowen spoke with persons at the Gay Information and Resources Hotline. In addition, Dr. Bowen was involved in an information exchange as a member of the AIDS Research Group. He was further aware that, as early as 1983, Dr. Kate Hankins (the Calgary Health Services Epidemiologist) interacted with the gay community in that capacity and disseminated the message regarding self-deferral.⁷⁴⁹
- **Saskatoon** - Dr. McSheffrey testified that he spoke to members of the gay community in Saskatoon some time before November 1983.⁷⁵⁰ Gens Helquist, an AIDS

⁷⁴⁷ Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13947-13957;

Ex. 332, Vol. 96, Part I, p. 40 (Minutes of Blood Program Committee Meeting, dated May 16, 1984); and

Ibid., p. 45 (Minutes of Blood Program Committee Meeting, dated June 20, 1984).

⁷⁴⁸ Evidence of Dr. Turner, Edmonton Centre Medical Director, pp. 7369-7375, 7545-7550, and 7654;

Evidence of Michael; Phair, Alberta Gay Panel, pp. 6811-6815; and

Evidence of Dr. Turc, former Edmonton Centre Medical Director, pp. 7369-7370.

⁷⁴⁹ Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 7751-7759.

⁷⁵⁰ Ex. 188, Vol. 70, Tab 3, p. 00012 (Handwritten Memo, dated November 14, 1983).

activist, testified that he was sent as the gay community representative to meet with Dr. McSheffrey in his office in February 1983. Mr. Helquist testified that he promised to do what he could to inform gay men with whom his organization was in contact not to donate blood.⁷⁵¹

- **Toronto** - Contact was made first in Toronto, by Dr. Derrick, who was in touch with Ed Jackson in early March 1983. Dr. Derrick also attended the April 8, 1983 meeting with the Toronto gay community to facilitate an information exchange between the CRCS and the gay communities nationwide.⁷⁵² On July 19, 1983, Dr. Herst represented the CRCS at a press conference to announce the formation of the AIDS Committee of Toronto (A.C.T.) and to provide information about AIDS and blood donation.⁷⁵³
- **Winnipeg** - Even prior to the receipt of Dr. Derrick's July 14, 1983 memo, Dr. Schroeder had agreed at a Cadham Provincial Laboratory meeting on June 13, 1983 to contact the gay community to ask its members to refrain from donating blood.⁷⁵⁴ She met with them before September 1983.⁷⁵⁵ In August 1983, Dr. Schroeder was involved in the production of a pamphlet produced by the Gay Coalition, which addressed the issue of blood donation by gay and bisexual men.⁷⁵⁶

⁷⁵¹ Evidence of Gens Helquist, AIDS activist, pp. 9718-9722.

⁷⁵² Ex. 616, CRC Vol. 13, Tab 45 (Memo from Dr. Derrick to Dr. Davey, dated March 8, 1983 re: AIDS and Donor Screening).

⁷⁵³ Ex. 620, CRC Vol. 17, Tab 8 (Memo from Dr. Herst to Dr. Perrault, dated July 19, 1983).

⁷⁵⁴ Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9804-9808;

Evidence of Winnipeg Gay Panel, pp. 10765-10768; and

Ex. 219, Vol. 74, Part I, p. 10 (Minutes of CPL/PMS Meeting, dated June 13, 1983).

⁷⁵⁵ Ex. 219, Vol. 74, Part I, p. 30 (Minutes of Blood Programme Advisory Committee Meeting, dated September 19, 1983, paragraph 7a).

⁷⁵⁶ Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9808-9822; and

Ex. 660, CRC Vol. 57, Tab 29 (Memo from Dr. Schroeder to Centre Staff, dated August 18, 1983, enclosing Gay Coalition Pamphlet on AIDS and Gay Male Blood Donations).

- **Saint John** - In the memo provided by Dr. Derrick to Dr. MacKay, no contact name for a member of the gay community was listed. Dr. MacKay testified that he attempted to contact a member of the gay community and looked at the Saint John telephone book for the name of a gay organization, but without success.⁷⁵⁷ The Canadian AIDS Society Panel, which testified in Saint John, conceded that it was difficult, even in 1994, to locate a gay organization in the telephone book. There is still no such organization listed in Saint John (but there is one listed in Fredericton).⁷⁵⁸
- **Vancouver** - In September 1982, an *Ad Hoc* AIDS Committee was formed. Members included Dr. Stout, who was then the Medical Director of the Vancouver Centre, and Dr. Bruce Douglas, who was the CRCS liaison with the gay community. He conveyed the CRCS message to the gay community soon thereafter and reported that there were no objections.⁷⁵⁹ In the Minutes of an AIDS Committee Meeting held on February 9, 1983, Dr. Stout advised that the appropriate contacts were already being made. The Vancouver CRCS Centre was aware that the gay community was being asked by physicians not to give blood⁷⁶⁰ and that the message of self-deferral was being widely disseminated in the gay community by a number of individuals. This included Dr. Hilary Wass, a member of AIDS Vancouver and the physicians' AIDS Care Team. Dr. Wass testified that Dr. Buskard acted as a liaison between the AIDS Care Team and the CRCS and maintained close ties with AIDS Vancouver, such that he was aware of their efforts beginning in late 1982 to educate gay men not to donate blood. Dr. Buskard also sought the advice from AIDS Vancouver as to whether the West End Denman Mall clinic should be closed. Given the widespread education efforts, it was believed that the gay community would not be donating blood at that clinic.⁷⁶¹

⁷⁵⁷ Evidence of Dr. MacKay, Saint John Centre Medical Director, pp. 11812-11819.

⁷⁵⁸ Evidence of CAS Panel (New Brunswick), pp. 11595-11597.

⁷⁵⁹ Public Submission (Letter from Dr. T.D. Stout to the Commissioner, dated March 10, 1995, including memo from Dr. Goldie to Dr. Boyes re: AIDS in Homosexual Males, dated November 12, 1982).

⁷⁶⁰ Ex. 111, Vol. 47, Tab 5, p. 052310 (Minutes of AIDS Committee Meeting, dated February 9, 1983).

⁷⁶¹ Evidence of Dr. Hilary Wass, pp. 49203-49295; and

Ex. 1291, Statement of Dr. Hilary Wass dated November 7, 1995.

- **Halifax** - Dr. Gorelick testified that he was in contact with someone, whose name he could not recall, at the "Gay Line"; however he could not recall the timing of this contact.⁷⁶² Insufficient evidence was elicited from the Halifax Gay Panel to determine exactly when Dr. Gorelick made this contact.
- **Hamilton** - At the Hamilton Centre, it was agreed that Dr. Ali, Deputy Medical Director, would make contact with members of the gay community.⁷⁶³ By July 20, 1983 Dr. Ali was in touch with the Hamilton United Gay Societies (hereinafter referred to as "HUGS") to reinforce the message that all members of high-risk were requested to voluntarily cease blood donations and to seek this group's advice as to how best this could be accomplished.⁷⁶⁴ HUGS advised high-risk individuals not to donate blood.⁷⁶⁵
- **Montreal** - Similarly, at the Montreal Centre, Drs. Sternback and Landry, both Deputy Medical Directors, were designated the task of contacting members of the gay community. They also were not called to testify about this issue. There is no evidence before the Inquiry as to when staff members at the CRCS Montreal Centre made contact with members of the local gay community.⁷⁶⁶
- **Ottawa** - Dr. Rock spoke to someone from the organization, "Gays of Ottawa", in 1983 but she could not recall the contents of the conversation or precisely when it occurred.⁷⁶⁷ No one from the organization, "Gays of Ottawa" testified before the Inquiry.

⁷⁶² Evidence of Dr. Gorelick, Halifax Centre Medical Director, pp. 13033-13034.

⁷⁶³ Evidence of Dr. Blajchman, Hamilton Centre Medical Director, pp. 19461 - 19462.

⁷⁶⁴ Ex. 1293 Letter from Dr. Anita Ali to Mike Johnson, Hamilton Gay Societies, dated July 20, 1983.

⁷⁶⁵ Ex. 1296 "Nurse dies of AIDS: No risk to patients-doctor", in The Spectator, dated August 10, 1983.

⁷⁶⁶ Evidence of Dr. Guevin, former Montreal Centre Medical Director, pp. 15643-15645, 15708.

⁷⁶⁷ Evidence of Dr. Rock, former Ottawa Centre Medical Director, pp. 24127-24128.

• **Charlottetown** - Although Dr. Ross was the only Prince Edward Island CRCS representative to give evidence, she did not hold the position of Medical Director during 1983. She had no information as to when Dr. Craig, who was Medical Director at the time, but is now deceased, made contact with the gay community.⁷⁶⁸

479. Evidence before the Inquiry as to CRCS contact with the gay community by other centres was incomplete.⁷⁶⁹ Nonetheless, it was clear that the message of voluntary self-exclusion was being disseminated.⁷⁷⁰ The March 10, 1983 self-exclusion message was reinforced in a second CRCS press release in July 1983.⁷⁷¹ The message was pervasive in the media.⁷⁷²

480. The media reported that the Haitian Community was outraged that it should be singled out, based only on ethnicity. In order to attempt to defuse the situation, Dr. Perrault met with members of the Haitian Community on April 13, 1983.⁷⁷³ Nonetheless, the Haitian community continued to respond to its inclusion in the high-risk group definition with great outrage. Haitians picketed the Ottawa and Montreal Centres.⁷⁷⁴ The sense of injustice felt by

⁷⁶⁸ Evidence of Dr. Ross, Charlottetown Centre Medical Director, pp. 13515-13516.

⁷⁶⁹ The current Medical Directors from Sudbury, Regina, Vancouver and Toronto were not called to testify on this issue. Where the task had been delegated, the delegates did not testify. Dr. Barr, former London Centre Medical Director, could not recall when contact was made by his Centre.

⁷⁷⁰ Evidence of Professor Tom Alloway, member of AIDS Panel, pp. 23751-23752, 23764-23765.

⁷⁷¹ Ex. 620, CRC Vol. 17, Tab 10 (CRCS Press Release, dated July 22, 1983).

⁷⁷² Ex. 659, CRC Vol. 56 (Newspaper Articles); and

Ex. 1050 (Additional Media Documents on Voluntary Self-Exclusion not contained in Volume 56 of the Commission Productions).

⁷⁷³ Ex. 697, Tab 13 (Minutes of a meeting held in Toronto between members of the Montreal Haitian Community and CRC BTS, dated April 13, 1983); and

Ex. 618, Vol. 15, Tab 20 (Notes of a meeting between Representatives of the Haitian Community, CRCS and Health and Welfare Canada, dated April 20, 1983).

⁷⁷⁴ Evidence of Dr. Rock, former Ottawa Centre Medical Director, pp. 24348-24349;

the Haitians escalated to a level whereby the Haitian Consulates General in Toronto and Montreal, as well as the Haitian Embassy in Ottawa formally made their grievance known to the CRCS.⁷⁵ There were complaints to the federal and provincial Human Rights Commissions.⁷⁶ The CRCS responded promptly by meeting with members of the Haitian community.⁷⁷ These negotiations resulted in the formulation of a draft communiqué to be signed by a representative of the CRCS, the federal government, and the Haitian community. Unfortunately, relations with the Haitian community were never completely restored and its representative never signed the joint communiqué.⁷⁸ It was clear that the message about voluntary self-exclusion reached the Haitian community and there is no evidence that this group donated blood notwithstanding.

481. The two measures by the CRCS, the public information campaign and direct contacts with members of high-risk groups, were aimed at providing information to high-risk donors outside the clinic, so that they would self-defer and not attend blood donor clinics.⁷⁹ As there were serious concerns about adverse reaction and political action by the Haitian and

Evidence of Dr. Guevin, former Montreal Centre Medical Director, pp. 15643, 15708; and

Ex. 618, CRC Vol. 15, Tab 5 (Agenda item 15 to BTS Advisory Committee Meeting of April 15, 1983).

⁷⁵ *Evidence of Dr. Davey, former Assistant National Director BTS, p. 27659.*

⁷⁶ *Ex. 618, CRC Vol. 15, Tab 28 (Letter from Francine Fournier Quebec Human Rights Commission to Keith Cardiff, dated April 29, 1983);*

Ex. 618, CRC Vol. 15, Tab 34 (Letter from H. Tellier to Francine Fournier, dated May 11, 1983);

Ex. 619, CRC Vol. 16, Tab 13 (Memo from Dr. Derrick to Dr. Perrault, dated June 2, 1983 re: Ontario Human Rights Commission); and

Ex. 623, CRC Vol. 20, Tab 21 (Letter from R.G.L. Fairweather, Canadian Human Rights Commission to George Weber, dated December 16, 1983).

⁷⁷ *Ex. 697, Tab 13 (Minutes of a Meeting held in Toronto between members of the Montreal Haitian Community and CRC BTS, dated April 13, 1983); and*

Ex. 618, CRC Vol. 15, Tab 20 (Report of a Meeting between Representatives of the Haitian Community, CRCS and Health & Welfare Canada on April 13, 1983, dated April 20, 1983).

⁷⁸ *Ex. 619, CRCS Vol. 16, Tab 16 (Memo from Eva Bart to Secretary General, dated June 6, 1983, enclosing draft Joint Communiqué).*

⁷⁹ *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27398-27399.*

gay communities, the CRCS had hoped that its initiatives to meet with members of high-risk groups to provide information would circumvent outcries of discrimination and the picketing of blood donor clinics.⁷⁸⁰ Unless the issue was carefully handled, there was a possibility that the adequacy of the blood supply could be affected. There were reports in both the United States and Canada that if the definition of high-risk groups to be excluded was too broad, members of the gay community would protest blood donor clinics⁷⁸¹ or would continue to donate in defiance of an exclusion which they considered to be discriminatory.⁷⁸² Consequently, the CRCS did not generically attempt to exclude all gay men from blood donation; nor was such a step justified on the basis of the scientific information at the time.⁷⁸³

⁷⁸⁰ Evidence of Dr. Sullivan, Administrator, Community Health Services, Nova Scotia Department of Health, pp. 12494-12496, 12725-12726;

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 23675;

Evidence of Dr. Guevin, former Montreal Centre Medical Director, pp. 15643, 15704, 15705; and

Ex. 382, Vol. 104, Part I, p. 98 (1983 Declaration from Gay and Lesbian Groups re: March 1983 Press Release).

⁷⁸¹ Evidence of Dr. Davey, former Assistant National Director BTS, p. 27670;

Evidence of Ed Jackson, AIDS Panel, p. 23675;

Evidence of Dr. Rock, former Ottawa Centre Medical Centre, pp. 24348-24349; and

Ex. 671, Tab 21 (Memo from Barb Stephens to Nursing Staff, dated March 18, 1983).

⁷⁸² Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22390-22391, 22541;

Evidence of Dr. Perrault, former National Director BTS, pp. 27554-27555, 28007-28017;

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27555-27556; and

Ex. 659, Vol. 56, Tab 34 (Medical Post Article entitled "Haitians Charge Racism Against Red Cross", by Terry Murray, dated April 19, 1983).

⁷⁸³ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30882-30886.

482. The CRCS's early meetings with the gay community defused the situation and the relationship between the CRCS and gay communities, for the most part, became cooperative.⁷⁸⁴ However, the magnitude of concern about discrimination is illustrated by the fact that even in 1995, the CRCS still experienced allegations of discrimination by the gay community because of questions about high-risk activity on its Donor Health Assessment Questionnaire, notwithstanding the present heightened awareness of the potential danger of a high-risk donor. In British Columbia, the CRCS was forced to close a blood donor clinic at the University of Victoria until a human rights complaint was resolved in favour of the CRCS. A similar complaint was made in Montreal at McGill University.⁷⁸⁵

483. The CRCS was very concerned about the potential impact accusations of discrimination would have on blood donor recruitment. Maintaining favourable public opinion is critical in an all-volunteer blood supply. Negative press could cause volunteer donors to lose faith in the CRCS as a humanitarian organization and boycott blood donor clinics. Media allegations of discrimination could permanently deter potential and regular donors.⁷⁸⁶

⁷⁸⁴ Evidence of AIDS Panel, pp. 23668-23691, 23707-23708.

⁷⁸⁵ Ex. 591, Tab 82 (Letter from University of Victoria Anti-Harassment Office to Len Lifchus, BDR, dated July 22, 1994);

Ex. 591, Tab 83 (Newspaper article from the Time-Colonist, dated July 29, 1994 entitled "Harassment Cancels UVic blood clinics"; article from the Vancouver Province, dated July 31, 1994 entitled, "No Gay Blood, Red Cross Says");

Ex. 591, Tab 84 (Letter from Dr. Pi, Vancouver Centre Medical Director to Mr. Strong, President of UVic, dated August 5, 1994);

Ex. 591, Tab 88 (Newspaper article from the Montreal Gazette, dated February 20, 1995 entitled, "Gays file complaints because they can't donate blood. ");

Evidence of Dr. Perrault, former National Director BTS, pp. 30884-30885; and

Evidence of William Mindell, CHS Member (Ontario Chapter), pp. 32410-32411.

⁷⁸⁶ Evidence of Dr. Perrault, former National Director BTS, pp. 27657-27660;

Ex. 562, Tab 47 ("AIDS Epidemic and Blood Safety: Changes in Attitudes From a Historical Perspective, by Bruce Evatt, at p. 82); and

Evidence of Dr. Guevin, former Montreal Medical Director, p. 15685.

Nonetheless, the CRCS took initiatives despite uncertain and evolving scientific knowledge, even when this was unpopular politically and high-risk groups were crying discrimination.⁷⁸⁷

3) Cooperation Between CRCS and Public Health Authorities

484. AIDS elicited unprecedented conflict between public health measures and issues of individual rights and politics.⁷⁸⁸ In general, the efforts of the CRCS were not substantially assisted by the public health authorities.⁷⁸⁹ While individual STD clinics and physicians participated in educating the public,⁷⁹⁰ there was no organized public health intervention. The roles of the various players were uncertain.⁷⁹¹ Despite its mandate across the country to prevent the spread of transmissible diseases, the public health authorities were less than instrumental in their actions. While they put forward general AIDS education, they left the counselling and education of high-risk individuals to physicians.⁷⁹² Physicians were not requested by public health authorities to determine whether their patients with AIDS or opportunistic infections were blood donors so that they could be counselled to refrain from blood

⁷⁸⁷ Evidence of Christopher Patterson, Board of Governors Panel, pp. 40111-40114.

⁷⁸⁸ Evidence of Dr. Francis, Epidemiologist, pp. 21833-21834, 21961; and

Ex. 553, Vol. 127, Tab 13 (NHF Chapter Advisory #2 Re: *Pneumocystis Carinii Pneumonia*).

⁷⁸⁹ Evidence of Mr. Ed Jackson, member of AIDS Panel, pp. 23715-23716 and 23874-23875;

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27071-27073, 27541-27543; and

Evidence of Dr. Perrault, former National Director BTS pp. 27534-27537.

⁷⁹⁰ In 1983 the CRCS initiated a program to involve physicians in the recruitment of healthy donors. See evidence of Dr. Herst, Toronto Centre Medical Director, p. 20225 and Ex. 512, Vol. 115, Part I, p. 50 ("Is There a Role for Physicians in the Recruitment of Blood Donors", dated 1983).

⁷⁹¹ Evidence of Dr. Pierre Lavigne, Medical Director of Clinical and Medical Affairs, Connaught Laboratories Limited, pp. 12662-12663.

⁷⁹² Evidence of Dr. Balram, Provincial Epidemiologist and Director of Health Promotion and Disease Prevention, New Brunswick, pp. 11347-11349.

donation in the future or so that the information could be provided to the CRCS for lookbacks.⁷⁹³ The BoB, which regulated the CRCS plasmapheresis operations, did not see fit to regulate the whole blood collection process until 1989.⁷⁹⁴ In a vacuum of defined roles and responsibilities, the CRCS often took an active role - alone.

485. The complacency demonstrated by all but a few public health officials⁷⁹⁵ may have been attributable to the fact that in 1983 Canada was 1½ years behind the U.S. in terms of AIDS incidence. Canada had one-quarter the incidence of AIDS per capita. While AIDS would not "stop at the border", it was widely believed that Canada would not be affected as seriously.⁷⁹⁶ It was maintained that the blood supply would be safer because of the all-

⁷⁹³ Evidence of Dr. Philip Berger, HIV Primary Care Physician, pp. 3053-3054; and Evidence of Roy West, former Provincial Epidemiologist, Saskatchewan Health, pp. 9335-9336.

⁷⁹⁴ Evidence of Dr. Furesz, BoB Panel, pp. 42739-42755; and Evidence of Dr. Boucher, BoB Panel, pp. 42755-42757.

See discussion of Regulation in Part I of this document.

⁷⁹⁵ Exceptions include Dr. John Waters who was invited to and did make comments on the CRCS August 1985 donor screening pamphlet and Dr. Kate Hankins, (Evidence of Dr. Larke, Deputy Medical Director, Edmonton Centre, pp. 6665-6667 and Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 7751-7759) and Dr. Wayne Sullivan (Evidence of Lucy Dobbin, Deputy Minister of Health for the Province of Nova Scotia, p. 12312).

⁷⁹⁶ Evidence of Dr. Furesz, BoB Panel, p. 43634; Evidence of Dr. West, former Provincial Epidemiologist, Saskatchewan Health, pp. 9301-9303; Evidence of Patricia Anne Hutchison, former member of Saskatoon AIDS Committee, p. 9121; Evidence of Dr. Perrault, former National Director BTS, pp. 26530, 28365-28368, 27546.

For example, it was known that the dimension of the I.V. drug abuse problem was much smaller in Canada than in the U.S. Indeed, the Canadian experience did not parallel the U.S. experience. By March 1985, there was only one reported case of AIDS due to I.V. drug abuse in Canada, while in the U.S. there were 1478 cases.

Ex. 743, Tab 4 (CDWR, dated March, 1985);

Evidence of Dr. Perrault, former National Director, BTS, pp. 27637-27638;

Evidence of Dr. Davey, former Assistant National Director, BTS, pp. 30897-30899.

volunteer donor base in Canada.⁷⁹⁷ These were some of the factors underlying a voluntary deferral approach to donor screening.

486. The first meeting of the National Task Force on AIDS, which later became NAC AIDS, took place on May 5, 1983 at LCDC. Invited participants at the first meeting included Dr. Derrick, Dr. Clayton, Dr. Boucher, Dr. Leclerc-Chevalier, Dr. Gill, Dr. Soskolne, Dr. Fanning, Dr. Allen, Dr. Gilmore, and Dr. Jessamine. Participants at later meetings included Dr. Furesz, Dr. Mathias, Dr. Perrault. This membership meant that there was representation on the Committee from the major players in the Canadian blood system: the CRCS, BoB, CBC, LCDC, and public health authorities. Dr. Allen served as the link with the CDC. Its mandate was as follows,

“to review the status of AIDS in Canada and in other countries, and to make recommendations to the Minister of Health & Welfare and other appropriate agencies which will lead to implementation of medical care, research and other strategies with regard to the diagnosis, treatment, control and prevention of AIDS in Canada.”⁷⁹⁸

487. NAC AIDS meetings facilitated important information exchange among the participants on issues such as AIDS research, incidence of AIDS in Canada and the U.S., case definitions, high-risk groups, risk groups, risk factors, laboratory testing, public education.

⁷⁹⁷ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27546-27550;

Evidence of Dr. Macpherson, former Medical Director of Health, City of Toronto, pp. 3477-3478;

Evidence of Dr. Gorelick, Halifax Centre Medical Director, pp. 12870-12872;

Evidence of Dr. Strawczynski, Hemophilia Treater, Montreal Children's Hospital, p. 31401;

Evidence of Dr. Remis, Montreal Epidemiologist, pp. 41326-41327;

Evidence of Doug Lindores, Secretary General, pp. 344-345; and

Evidence of Dr. Furesz, BoB Panel, p. 43634.

⁷⁹⁸ Ex. 682, Vol. 147, Tab 2 (*Minutes of Meeting of National Task Force on "AIDS", dated May 5, 1983*);

Ex. 682, Vol. 147, Tab 3 (*Mandate of National Task Force on "AIDS", dated May 5, 1983*); and

Ex. 682, Vol. 147, Tab 6 (*Minutes of NAC AIDS Meeting, dated September 30, 1983*).

reporting. NAC AIDS met regularly throughout the 1980's. The CRCS took advantage of its expertise and sought its advice, consultation, and approval of its members on issues such as the appropriateness of the CRCS Press Release of March 10, 1983, donor screening measures, and the implementation of and ethical issues surrounding anti-HTLV-III testing.⁷⁹⁹

488. Similarly, in June 1983, the Associate Deputy Minister of Health, Institutional Health Services, in the Province of Ontario established an advisory committee on AIDS, which became known as PAC AIDS. This Committee had a similar role to NAC AIDS. The Terms of Reference of PAC AIDS were to advise the Ontario Ministry of Health on the following five issues:

1. Service Needs - treatment clinics, designated referral centres, safety of personnel;
2. Communication with the professional community;
3. Research;
4. Special problems of the users of blood products, particularly Factor VIII; and
5. To maintain a liaison with NAC AIDS;⁸⁰⁰

489. This mandate was expanded in 1984 to include:

1. monitoring the caseload of ARC/AIDS patients and the availability of health services for these patients;
2. monitoring and critically appraising information on AIDS;

⁷⁹⁹ Ex. 682, Vol. 147, Tab 2 (*Minutes of Meeting of National Task Force on "AIDS", dated May 5, 1993*);

*Ex. 682, Vol. 147, Tab 6 (*Minutes of Meeting of NAC AIDS dated September 30, 1993*);*

*Ex. 682, Vol. 147, Tab 16 (*Minutes of Meeting of NAC AIDS dated November 9, 1993*);*

*Ex. 684, Vol. 148, Tab 18 (*Minutes of Meeting of NAC AIDS dated October 9, 1984*); and*

*Ex. 686, Vol. 149, Tab 2 (*Minutes of Meeting of NAC AIDS dated October 9, 1985*).*

⁸⁰⁰ Ex. 37, Vol. 15, Tab 1 (*Memo from Boyd Suttie, dated June 2, 1983 re: Advisory Committee on AIDS*).

3. reviewing and evaluating research priorities;
4. considering issues concerning professional attitudes and support to AIDS/ARC patients; and
5. advising on all matters referred by the Ministry⁸⁰¹

490. The representatives of the first Committee included Ministry staff, Dr. Fanning, a member of the Ontario Hospital Association, a member of the Ontario Medical Association, and Dr. Derrick from the CRCS.⁸⁰² The Committee made direct contact with members of the CRCS highest risk groups - gay men and Haitians through A.C.T., which had the mandate to represent all higher-risk groups.⁸⁰³ In November 1983, PAC AIDS also began work on an information pamphlet on the issue of AIDS for physicians, dentists, hospitals, public health workers, and laboratories which was to include a section, drafted by Dr. Derrick, on blood and blood product issues. This was completed by May 1984.⁸⁰⁴ PAC AIDS also considered the ramifications of Anti-HIV testing in Canada by the CRCS and for diagnostic purposes.⁸⁰⁵ Throughout the 1980's other provinces convened AIDS committees with similar mandates to advise the provincial ministers of health on AIDS-related issues and monitor AIDS in the province.⁸⁰⁶

⁸⁰¹ Ex. 39, Vol. 18, Part I, Tab 15 (*Minutes of Ministers' Meeting with Dr. Fanning, dated May 24, 1984*).

⁸⁰² Ex. 37, Vol. 15, Tab 2 (*Memo from Bill Hogle to Graham W.S. Scott, Q.C., Deputy Minister, dated June 6, 1983*); and

Ex. 39, Vol. 18, Part I (Letter from Dr. Fanning to Committee Members, dated July 4, 1983).

⁸⁰³ Ex. 35, Vol. 15, Tab 4 (*Minutes of PAC AIDS Meeting, dated September 16, 1983*).

⁸⁰⁴ Ex. 35, Vol. 15, Tab 7 (*Minutes of PAC AIDS Meeting, dated November 9, 1983*);

Evidence of Dr. Fanning, former Chair of PAC AIDS, pp. 2114-2122;

Ex. 35, Vol. 15, Tab 9 (Minutes of PAID AIDS Meeting, dated May 15, 1994); and

Ex. 39, Vol. 18, Part 1, Tab 13 (Letter from Dr. Fanning to Dr. Suttie, dated March 15, 1984).

⁸⁰⁵ Ex. 35, Vol. 15, Tab 10 (*Minutes of PAC AIDS Meeting dated April 25, 1985*).

⁸⁰⁶ Ex. 342, Vol. 93, p. 13 (*December 5, 1985 Minutes of AIDS Sub-Committee, Advisory Committee on Immunization*);

4) Voluntary Self-Exclusion

491. The CRCS acted to implement a policy of voluntary self-exclusion of high-risk groups in March 1983.⁸⁰⁷ On March 10, 1983, the CRCS issued a press release asking members of groups at high risk for developing AIDS to voluntarily exclude themselves from giving blood. Those persons were listed as follows:

- persons diagnosed with AIDS;
- sexual partners of AIDS patients;
- sexually active homosexual or bisexual men with multiple partners;
- recent Haitian immigrants;
- current or past drug abusers; and
- sexual partners of persons at high risk of AIDS.⁸⁰⁸

Ex. 293, Vol. 88, Tab 3, pp. 67-68 (November 6, 1987 Tas Force Representing A.I.D.S. Established by the Government of Nova Scotia - Terms of Reference);

Ex. 293, Vol. 88, Tab 4, pp. 85-86 (March 8, 1988 Press Release);

Ex. 326, Vol. 89, Tab 2, p. 12 (December 1988 Report of the Prince Edward Island AIDS Advisory Committee to the Minister of health and Services) [This Committee first met in 1987];

Ex. 241, Vol. 73, Pt. III, pp. 29-30 (March 2, 1988 Memorandum from J. Kaufman to Hon. Parisiuk);

Ex. 91, Vol. 39, Tab 4, (January 12, 1983 Minutes of Auto-Immune Deficiency Syndrome (AIDS) Committee);

Ex. 131, Vol. 56, Tab 6 (February 20, 1991 Minutes of Alberta Advisory Committee on AIDS) [First Meeting];

Ex. 204, Vol. 67, Pt. 1, p. 136 (October 9, 1985 Article entitled "Provincial AIDS Committee to be established", The Times, Assiniboia, Sask.); and

Ex. 204, Vol. 67, Pt. 1, p. 188 (Letter from G. Taylor to The Honourable Murray J. Elston).

⁸⁰⁷ Ex. 617, CRC Vol. 14, Tab 3 (CRCS Press Release, dated March 10, 1983).

⁸⁰⁸ Ex. 617, CRC Vol. 14, Tab 3 (CRCS Press Release, dated March 10, 1983).

The fact that this press release received wide media attention is evidenced by the number of newspaper articles which discussed it in the following weeks.⁸⁰⁹

492. The CRCS took steps over the next few months to ensure that the voluntary self-exclusion message was widely circulated. As previously described, it made direct contact with members of the gay and Haitian communities in order to educate them.⁸¹⁰ Other actions included participation in the first NAC AIDS Meeting on May 5, 1983 (in which an informational statement on AIDS was prepared for transmission to public health authorities),⁸¹¹ radio and television interviews⁸¹² and meetings with public health authorities to exchange information and to coordinate public health information and statements⁸¹³. Following a May

⁸⁰⁹ Ex. 659, CRC Vol. 56 (*Newspaper Articles*); and

Ex. 1050 (*Additional Media Documents on Voluntary Self-Exclusion not contained in Volume 56 of the Commission Productions*).

⁸¹⁰ These efforts were discussed in greater detail in the previous section. But see Ex. 617, CRC Vol. 14, Tab 20 and 21 (*Minutes and Summary of Meeting of Ad Hoc Working Group on AIDS*, dated March 29, 1983);

Ex. 616, CRC Vol. 13, Tab 45 (*Memo from Dr. Derrick to Dr. Davey, dated March 8, 1983*);

Ex. 618, CRC Vol. 15, Tab 10 (*Summary of Proceedings of a Meeting concerning Informational Exchange on AIDS between Representatives of the CRCS and of Toronto Homosexual Groups, April 8, 1983*);

Ex. 618, CRC Vol. 15, Tab 20 (*Report of a meeting between representative of the Haitian community, CRCS and Health & Welfare Canada on April 13, 1983, dated April 20, 1983*);

Ex. 618, CRC Vol. 15, Tab 25 (*Memo from Dr. Derrick to All Centre Medical Directors and Members of CRC BTS Ad Hoc Working Group on AIDS re: AIDS: Update on Action Taken with Reference to Recommendations made at CRC BTS Medical Directors Meeting, March 24, 1983, dated April 23, 1983*); and

Ex. 619, Vol. 16, Tab 12 (*Memo from Dr. Derrick to All Centre Medical Directors and Members of CRCS BTS Ad Hoc Working Group on AIDS re: AIDS Update as of May 13, 1983, dated June 2, 1983*).

⁸¹¹ Ex. 618, CRC Vol. 15, Tab 30 (*Minutes, National Task Force on AIDS, taken place May 5, 1983, dated May 10, 1983*).

⁸¹² Ibid, Tab 39 (*Article by Dr. Derrick entitled: "AIDS and Canadian Blood Resources", dated May 17, 1983*).

⁸¹³ Ex. 619, CRC Vol. 16, Tab 5 (*Memo from Bill Mindell to Sandy MacPherson, Anne Moon, Richard Fralick, dated May 26, 1983*); and

1983 meeting, Bill Mindell of the Toronto Board of Health created and the CRCS assisted in responding to, potential media questions on AIDS.⁸¹⁴

493. On July 22, 1983, the CRCS issued a second press release, reaffirming its position on voluntary self-exclusion.⁸¹⁵ Throughout this period of time, Dr. Derrick was occupied full-time in dealing with AIDS public education.⁸¹⁶

494. Voluntary self-exclusion of high-risk groups was acknowledged by epidemiologists to be an effective screening procedure even as late as 1987.⁸¹⁷ It too was a tool used by the voluntary blood banks in the United States.⁸¹⁸ While the Americans believed that voluntary self-exclusion would be successful,⁸¹⁹ the CRCS believed it would be even more effective in Canada because of its all-volunteer donor base and lower risk population. Because of the

Ibid, Tab 6 (Summary of Proceedings of a Meeting Representatives of the City of Toronto Department of Public Health, the U of T AIDS Research Group and the CRC BTS, dated May 26, 1983).

⁸¹⁴ *Ibid, Tab 27 (Letter from Bill Mindell to Dr. Naylor, dated June 16, 1983); and*

Ex. 620, CRC Vol. 17, Tab 18 (Memo from Eva Bart to Divisional Commissioners/Director General dated July 26, 1983 re: Potential Media Questions Concerning AIDS).

⁸¹⁵ *Ibid, Tab 10 (CRCS Press Release, dated July 22, 1983).*

⁸¹⁶ *Ibid, Tab 40 (Memo from Dr. Perrault to Acting Secretary General, dated July 4, 1983).*

⁸¹⁷ *Ex. 1001, Vol. 247, Tab 21 (CDWR, dated March 1985); and*

Ex. 1274 ("Transmission of HIV and Natural History of AIDS", by Randal Coates and Kenneth Johnson).

⁸¹⁸ *Ex. 660, CRC Vol. 57, Tab 25 (Memo from Dr. Davey to all Medical Directors, dated January 24, 1983); and*

Ex. 554, Vol. 128, Part I, Tab 2 (HHS CDC documents re: "Work Group to Formulate Recommendations for the Prevention of AIDS", January 4, 1983).

⁸¹⁹ *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22382, 22407-22408, 22542-22545.*

altruistic motivation of volunteer donors it was a reasonable belief that donors would have no incentive to be untruthful about their high-risk status.⁸²⁰

495. As the policy of voluntary self-exclusion had been widely disseminated, the CRCS believed that potentially high-risk donors were refraining from blood donation. It is only in retrospect with heightened societal awareness about the gay and bisexual communities, and the result of testing introduced in 1985, that it becomes apparent that the CRCS could not possibly have reached all high-risk individuals. Bisexual men were most difficult to reach.⁸²¹ Nevertheless, it is clear that many high-risk individuals did refrain from donation:

I believe that the self-exclusion system was probably working reasonably well. Very frankly, sir, I am not sure, given what Mr. Jackson has testified about the various outer rings of the concentric circles that comprised the gay community, my guess is that the stories that were in the newspapers and on TV and radio, unfair and distorted as those stories were, may have done more than ACT was able to do, or the Red Cross was able to do. I think it was probably the media that got the story out mainly. But, nevertheless, it got out, and I think the self-exclusion program is working...

By and large people got the message. If they hadn't, the catastrophe would have been a whole lot worse than it was.⁸²²

⁸²⁰ Evidence of Dr. Herst, *Toronto Centre Medical Director*, pp. 21420-21421;

Evidence of Professor Tom Alloway, *member of AIDS Panel*, pp. 23617-23618;

Evidence of Dr. Sullivan, *Administrator, Community Health Services, Nova Scotia Department of Health*, pp. 12494-12496, 12725-12726; and

Evidence of Ed Jackson, *member of AIDS Panel*, p. 23690.

⁸²¹ Evidence of Dr. Turc, *former Edmonton Centre Medical Director*, pp. 7374-7375, 7531;

Evidence of Dr. Huntsman, *St. John's Centre Medical Director*, pp. 13899-13903;

Evidence of Dr. Zuck, *former Director of Division of Blood and Blood Products, FDA*, p. 22382, 22544-22546; and

Evidence of Ed Jackson, *member of AIDS Panel*, pp. 23296-23299, 23308-23309.

⁸²² Evidence of Professor Tom Alloway, *member of AIDS Panel*, pp. 23764-23766.

Given the perceived risk of AIDS at the time, these measures which were undertaken were believed to be a sufficient and appropriate response.⁸²³

5) Bag Tagging/Black Dotting/L59 Coding/Red Taping

496. The practice of bag tagging/black dotting/L59 coding was in effect at all CRCS centres even before the advent of AIDS. Where a donor did not declare himself or herself to be a member of a high-risk group, but the clinic staff knew or suspected that a donor was high-risk, the donation would be discarded out of an abundance of caution.⁸²⁴ Nurses always had discretion to discard a blood donation when they believed it ought not to go into the blood supply and they wanted to avoid a confrontation at the clinic. Because there was no test for AIDS and no way to determine the accuracy of a nurse's hunch, a donor would not know that his or her blood was to be destroyed and not used for transfusion.⁸²⁵ While bag-tagging

⁸²³ Evidence of Michel Chretien, former Chair of Royal Society of Canada Steering Committee, pp. 49023-49025;

Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 21420-21421;

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27593, 30879-30881;

Evidence of Janet Jones, member of Board of Governors, pp. 40356-40358;

Ex. 697, Tab 30 (Article in the Montreal Gazette, dated February 19, 1985 per Dr. Gilmore);

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9777-9778; and

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22407-22408.

⁸²⁴ Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8397-8399, 8611-8615; and

Evidence of Dr. Guevin, former Montreal Centre Medical Director, p. 15699.

⁸²⁵ Evidence of Dr. Turc, former Edmonton Centre Medical Director, pp. 7398-7399; and

Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 7805-7806.

occurred at all centres in one form or another, it was done rarely and with discretion. National office was aware of this practice and condoned it.⁸²⁶

497. Paragraph 75(b) of the Minutes of the March 24 and 25, 1983 Medical Directors Committee Meeting reads:

Dr. Perrault stated that blood collected from high risk group donors is not to be singled out at the moment. Some Centres had it held in Quality Control testing and others had disposed of it...⁸²⁷

Throughout his evidence, Dr. Perrault asserted that he did not intent to prohibit the practice of bag tagging at the March 1983 Medical Directors Meeting. Dr. Perrault testified that he never suggested that the *practice* of discarding blood from known or suspected high-risk donors should be discontinued, only that the *procedure* should be uniform and appropriate.

498. Most centres engaging in this practice were marking the donation bag with a special tag or dot to ensure that the blood was not used. However, this practice was not uniform and some centres were making use of a laboratory ("L") code, which was entered into the Alpha Registry donor list, and therefore, onto the donor's permanent file. In Dr. Perrault's view, this was not appropriate since there was, as yet, no laboratory reason to defer the donor. There was no AIDS test. The danger of having an "L" code entered onto the Alpha Register was that a registrar might confront the donor when there was no laboratory reason to do so. Simply marking the blood bag would ensure that there was no record on the donor file but that the

⁸²⁶ Evidence of Dr. Perrault, former National Director BTS, pp. 27581-27583; and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27563-27567, 27755, 27737-27832.

Ex. 618, CRC Vol. 15, Tab 39 ("AIDS and Canadian Blood Resources" by Dr. Derrick, dated May 17, 1983).

⁸²⁷ Ex. 617, CRC Vol. 14, Tab 16 (Minutes of Medical Directors Committee Meeting, dated March 24-25, 1983, paragraph 75(b)).

donation would not be used for transfusion.⁸²⁸ Dr. Perrault stated that this was his position in 1983 and that it continued to be his position when the issue was raised once again in 1990.⁸²⁹

499. Although the words as minuted in the Medical Directors meeting are open to the interpretation that the practice of bag-tagging was to stop, no medical director so interpreted it. No centre discontinued its bag-tagging practice following this meeting, a fact which demonstrates that no one understood Dr. Perrault to have suggested that they do so. Dr. Bowen and Dr. Buskard confirmed that this practice was within the knowledge of the national office.⁸³⁰ Moreover, Drs. Gorelick and Schroeder testified that they never received a directive from National office that this practice should stop.⁸³¹

500. Dr. Huntsman ventured to state that the words as minuted in the Medical Directors meeting were strangely out-of-character for Dr. Perrault. He called it an aberration and stated that the recorded statement seemed very unlike Dr. Perrault.⁸³²

501. The evidence on this issue supports the view that the minutes did not accurately characterize the discussion, and that the CRCS did not intend such a prohibition, nor did it have that effect:

⁸²⁸ Evidence of Dr. Perrault, former National Director BTS, pp. 27551-27583, 27737-27832; and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27569-27570.

⁸²⁹ Ex. 335 (Memo from Dr. Perrault, Deputy Secretary General of Blood Services, to Medical Directors, dated August 8, 1990, and excerpt of Minutes of Medical Directors Committee Meeting, dated October 25-26, 1990, paragraph 110); and

Evidence of Dr. Perrault, former National Director BTS, pp. 27791-27806.

⁸³⁰ Evidence of Dr. Bowen Calgary Centre Medical Director, pp. 3105-3106; and

Evidence of Dr. Buskard, Clinical Professor of Medicine, pp. 5756-5758.

⁸³¹ Evidence of Dr. Gorelick, Halifax Centre Medical Director, p. 13044; and

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10178-10180.

⁸³² Evidence of Dr. Huntsman, St. John's Centre Medical Director, p. 14197.

- **Calgary** - Dr. Bowen testified that a black dot system was in use in early 1983 and continued long after the March 1983 Medical Directors Meeting, with the knowledge of Dr. Davey:⁸³³

...Early in 1983 the Clinic nurses had a great deal of experience on the front lines and soon got to know whether a donor looked to be an unwell donor.

The Clinic staff were made very aware of what the high risk groups were. One made it very clear that new tattoos was very bad, that certainly the nurses were informed that anybody with lymphadenopathy that was obvious, and there are lymph nodes in the elbow near where you put a needle, if you see lumps or bumps and the donor claims to be well, if you see new tattoos, if you see needle marks, if you see obvious high risk behaviour being admitted to or suspected, you can indicate that on the bag and no questions asked, and the bag will not make it into the transfusion system...

...That was a black dot system. A final safety zone, if you like, in that if you had a gut reaction as a front line clinic phlebotomist that something was not well and this donor, for whatever reason, even if it was gut reaction, that rather than having to document what that might be, simply put a black dot on, and no further questions were asked, the unit should not go into transfusion.⁸³⁴

- **St. John's** - Dr. Huntsman testified that at least as early as February 1983, nurses had the discretion to dispose of a unit of donated blood if they suspected that a donor was a member of a high-risk group.⁸³⁵
- **London** - At the London Centre, a slightly different procedure was in place. If a nurse suspected that a donor was a member of a high-risk group, he or she was to consult with Dr. Barr as to whether or not the blood ought to be used:

...I knew that was a procedure that was being done at some Centres and I knew there was interest in doing it at our Centre. My problem with it was that I didn't think it could be done reliably. I did not feel it was appropriate to have someone simply designate someone being from a high-risk group by looking at them and seeing the way they answered questions.

⁸³³ Evidence of Dr. Bowen, *Calgary Centre Medical Director*, pp. 7805-7806, 7813-7815, 8106; and Ex. 620, *CRC Vol. 17, Tab 19 (Memo from Dr. Bowen to Dr. Davey, dated July 26, 1983)*.

⁸³⁴ Evidence of Dr. Bowen, *Calgary Centre Medical Director*, pp. 7805-7806.

⁸³⁵ Evidence of Dr. Huntsman, *St. John's Centre Medical Director*, pp. 13885-13887.

The risk was, of course, that we wouldn't pick up on these people, so I made it clear that should there be these concerns and they felt comfortable about them and they could validate them that they must approach me about them. I didn't want to have something unsafe going through the system, but I didn't want to simply have it thrown out and simply be labelled.

In actual fact -- and my memory is vague on this -- I think there might have been a couple where people came up with such compelling argument that I felt it was appropriate to take that route, but it was very restricted and those were the sort of guidelines.⁸³⁶

Dr. Perrault testified that this meant that rather than taking the exercise of discretion away from the nurses, Dr. Barr was asking them to validate their discretion with him; it was broad-based discretion and he was at one end of the broad spectrum.⁸³⁷

- **Toronto** - Dr. Herst testified that she did not know whether nurses were in the practice of flagging the blood "Not for Transfusion" upon mere suspicion of a donor being at high-risk.⁸³⁸ Certainly, she was aware that if a donor divulged the information that he or she was at high risk, the donation would be flagged "Not for Transfusion"⁸³⁹:

...Whether this "Not for Transfusion" tag was also used by the nursing staff on the basis of a suspicion I can't confirm.⁸⁴⁰

- **Saskatoon** - Dr. McSheffrey testified that this was a longstanding practice at his Centre and that there was no specific National direction about it⁸⁴¹.

⁸³⁶ *Evidence of Dr. Barr, former London Centre Medical Director, pp. 19722.*

⁸³⁷ *Evidence of Dr. Perrault, former National Director BTS, pp. 27769-27770.*

⁸³⁸ *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20355-20357, 27775-27781.*

⁸³⁹ *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20498-20500; and*

Ex. 512, Vol. 115, Part I, p. 147 (Memo from Dr. Herst to Dr. Wrobel, dated March 22, 1983).

⁸⁴⁰ *Evidence of Dr. Herst, Toronto Centre Medical Director, p. 20500.*

⁸⁴¹ *Ex. 188, Vol. 70, Tab 3, p. 00014 (Memo from Sandra Renner to Dr. McSheffrey and response, dated June 14, 1983); and*

I don't think there was anything that was specific about this. This is a practice that has gone on in the Blood Transfusion Service for as long as I can remember, that if a nurse felt that there was some reason why that unit might not be appropriate, they were first of all to try and talk the donor out of donating.

If there was an insistence on it, rather than disrupt the Clinic, that they would take the unit and mark it. That was before AIDS occurred. This was just an extension of that.⁸⁴²

- **Winnipeg** - Dr. Schroeder testified that if nurses at clinics felt that a donor might be at high risk, they ensured that the unit was described as contaminated and was discarded.⁸⁴³ While it was done, these occasions were rare:

...I don't think anybody specifically had instructions. We didn't have written guidelines as to what they should do or shouldn't do in these circumstances. It was to be brought to the attention of their Nursing Manager and then upwards to one of the Medical Directors to try to determine what would happen. These were very, very rare occasions that I can recall.⁸⁴⁴

- **Ottawa** - Dr. Rock testified that there was such a procedure in the Ottawa Centre if a suspected high-risk donor insisted upon donating notwithstanding being asked to self exclude.⁸⁴⁵
- **Halifax** - Dr. Gorelick testified that a blood donation bag was tagged in Halifax in these circumstances:

...This was an area which was explored with the group of nurses and clear instructions were given to them. It was amplified as to what level of authority they had because they did in fact feel some degree discomfort to venture into a new area.

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8397-8399.

⁸⁴² *Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8614-8615.*

⁸⁴³ *Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10072-10075.*

⁸⁴⁴ *Ibid, p. 9803.*

⁸⁴⁵ *Evidence of Dr. Rock, former Medical Director, Ottawa Centre, p. 24356.*

Therefore, they were adequately instructed and informed that if they did have intuitive feelings or made a seasoned judgment that someone shouldn't be allowed to give, then they should in fact tag the bag for destruction.⁸⁴⁶

- **Charlottetown** - This same procedure was in place at all Halifax mobile clinics. All blood collected in Prince Edward Island was done by mobile clinics out of the Halifax Centre. Consequently, all blood collected in PEI was subject to the bag tagging procedure as well, although Dr. Ross was not questioned about this when she testified.⁸⁴⁷
- **Saint John** - Dr. MacKay also testified that in Saint John, he was well aware of the professional responsibility that clinic nurses felt and he supported their desire to code donations of donors who they believed were in a high-risk group:

If a member of the clinic staff was of the opinion that a prospective donor was in a high-risk group, the donation would not be used. It would be coded, so that it would not enter the blood supply...

...It was an initiative of the nurses. I discussed it with them and they felt very strongly. They had a professional responsibility to do this, so I condoned the practice. I permitted it. I knew it was happening. I did not interfere with it. I had some reservations about the practice.⁸⁴⁸

- **Montreal** - Dr. Guevin testified that a nurse was first to ask a donor who was suspected of being a member of a high-risk group to self-exclude. If the nurse could not convince a donor not to donate, the word "discard" was written on the registration form or a sticker was used. The donation was not used.⁸⁴⁹ This was a practice in use at the Montreal Centre in various circumstances when the nurse thought the donor ought not to donate, even before AIDS came to the forefront.

⁸⁴⁶ Evidence of Dr. Gorelick, *Halifax Centre Medical Director*, p. 12890.

⁸⁴⁷ Evidence of Dr. Gorelick, *Halifax Centre Medical Director*, pp. 12889-12891.

⁸⁴⁸ Evidence of Dr. MacKay, *Saint John Centre Medical Director*, pp. 11832-11833.

⁸⁴⁹ Evidence of Dr. Guevin, *former Montreal Centre Medical Director*, p. 15678.

- **Québec City** - Dr. Hebert Testified that, as early as 1983, if a nurse was suspicious, she would ensure that the blood bag could not be used.⁸⁵⁰
- **Edmonton** - While Dr. Turc was not asked whether he recalled the March 1983 Medical Directors Committee Meeting, or referred to Dr. Perrault's comment in the minutes, he stated:

DR. TURC: ...We had what we call a lab alert code, which was a computer code, which would allow the donor to come again and to have his blood collected again, but as soon as you were with this alert code your blood could not be used.

We did that during all the period where we had some suspicion that someone should not give, either because we were called by the physician or because the donor phoned after and said, "Look, I gave blood, I should not", or because a donor was telling us, "I saw so-and-so at your clinic, and he's gay". We had to act indiscriminately on all these assumptions. Probably some of these people were not coded properly. Again, you had to err on the side of caution.

That's why the donors were not informed, because we had absolutely no ground to know if it was true or not. We had no testing available. That's the system which was in place...

MR. DOUCETTE: That that donor would not be told not to come back, but the system was such that if the person was not seen to be high risk by the staff dealing with him or her that day, the computer would recognize the donor's name and alert the laboratory not to use that unit of blood.

DR. TURC: That is correct.⁸⁵¹

- **Vancouver** - Dr. Buskard testified that his Centre staff were also using a lab alert code⁸⁵².

The "L" code is the one we have discussed earlier, where we had made a decision not to use somebody's blood. This initially was informal in our Centre, and then it became formalized as an "L" code, and then it was finally given a number, L-59. "L" coding basically meant that we were tagging and destroying blood in those days.

⁸⁵⁰ Evidence of Dr. Hebert, Québec Centre, Medical Director, pp. 15238-15242.

⁸⁵¹ Evidence of Dr. Turc, former Edmonton Centre Medical Director, pp. 7399-7400.

⁸⁵² Ex. 620, CRC Vol. 17, Tab 39 (Memo from S. Whynot to A. Adatia, dated August 18, 1983).

As you can see, if a nurse was going to defer a donor on a "C" code, generally speaking she would try to explain it to the donor...⁸⁵³

...I don't think there was any confusion in the Centre in terms of what our purpose was. Our purpose was to not have homosexual individuals donate. So we were carrying forward a three-pronged attack: the media, the physicians, and the AIDS Vancouver community.

Finally I come back to the thing we discussed earlier, and that was the bag tagging which was going on at that time with a clinical assessment by the nurse.

The fourth issue was that we were asking donors if any of the issues in the plasticized information placard applied to them when they came to donate.

I think we were hitting it from a variety of directions at that time, and I don't think we were confused on what we were doing, but perhaps this communication here makes it appear that way...⁸⁵⁴

...

...The tagging procedure was aimed at any individual who might present themselves as a blood donor and something was noted clinically by the nurse which gave her the feeling that the donation should not be used for transfusion...

If my nurse says to me that she's unhappy with a blood donation, I don't want you to have it and I don't want to have it myself. I think you have to rely upon the good clinical judgment of our nurses in this situation. It is not a dishonest thing to do in terms of the gay population and that's not really what we were focusing on after we got the co-operation of the gay community. It was really the chance of a person coming into the clinic who the nurses noted, for whatever clinical reason, that there was a problem.

I submit to you that you would not want that unit of blood if my nurse said she wasn't happy with it. I submit you wouldn't want to give it to your children either.⁸⁵⁵

Dr. Buskard testified that bag tagging was effective at his Centre since the infectious marker rate was greater in the tagged bags than those that were not tagged.⁸⁵⁶

⁸⁵³ *Evidence of Dr. Buskard, former Vancouver Centre Medical Director, pp. 5534-5535.*

⁸⁵⁴ *Evidence of Dr. Buskard, former Vancouver Centre Medical Director, pp. 5655-5656.*

⁸⁵⁵ *Ibid, pp. 5883-5884.*

⁸⁵⁶ *Ibid, pp. 5642-5643.*

- **Hamilton** - Dr. Blajchman testified that an L59 laboratory code was used at the Hamilton Centre:

Well, it's this issue that I believe has been addressed by other Medical Directors at these Hearings. This is the issue of discretion used by a nurse who is involved in the screening of the donor or the collection of blood from a donor, where she suspects that the donor may not have been entirely truthful about the questionnaire, the questions being asked of them.

What we have done is we have used this code to alert people that there is a problem, but what the FDA inspector observed is that we should be definitive in our -- if we have reason to suspect that a donor has not been entirely truthful, then we should defer that donor permanently.⁸⁵⁷

502. This review demonstrates that all Medical Directors who were asked about bag tagging testified that it was practiced at their centres during the 1980's. In summary, the practice of bag tagging was both condoned and authorized by National Office.⁸⁵⁸ Medical Directors testified that National Office knew about the procedure in effect at their centres and made no attempt to stop it.⁸⁵⁹ Consistent with this fact is Dr. Derrick's May 1983 discussion at the Nursing Managers Meeting⁸⁶⁰ and his May 17, 1993 article entitled *Acquired Immune Deficiency Syndrome (AIDS) and Canadian Blood Resources*:

⁸⁵⁷ Evidence of Dr. Blajchman, Hamilton Centre Medical Director, pp. 19025-19026.

⁸⁵⁸ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27753-27754, 30901-30903, 30909-30911, 30914.

⁸⁵⁹ Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 8105-8106;

Evidence of Dr. Gorelick, Halifax Centre Medical Director, P. 13044;

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10179-10180; and

Ex. 620, CRC Vol. 17, Tab 19 (Memo from Dr. Bowen to Dr. Davey, dated July 26, 1983).

⁸⁶⁰ Ex. 618, CRC Vol. 15, Tab 33 (Minutes of Nursing Managers Meeting, Appendix III, dated May 10-12, 1983).

Reviewing the measures which have been implemented by the CRC to reduce the risk of transmission of AIDS by transfusion they are:...Destruction of units drawn from donors who may prove to be at risk.⁸⁶¹

503. Bag tagging had been traditionally used in a wide variety of circumstances, not just to exclude known or suspected members of the gay community from donating.⁸⁶² For example, if a donor with a known medical condition (which made his or her donation unsafe for transfusion) was belligerent about donating, the nurse would accept the donation and tag the blood bag to avoid a confrontation at the clinic.⁸⁶³

6) The Good Health Approach to Screening for AIDS Symptoms

504. There were two schools of scientific thought as to whether symptom-specific questions would be effective in eliminating donors at risk for AIDS. Many European countries,

⁸⁶¹ *Ibid, Tab 39 (Article by Dr. Derrick entitled "Acquired Immuno-Deficiency Syndrome (AIDS) and Canadian Blood Resources", dated May 17, 1983).*

⁸⁶² *Evidence of Dr. Turc, former Edmonton Centre Medical Directors, and Dr. Turner, Edmonton Centre Medical Director, pp. 7399-7401;*

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8611-8614;

Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 21421-21422;

Evidence of Dr. Perrault, former National Director BTS, and Dr. Davey, former Assistant National Director BTS, pp. 30912-30913;

Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 7805-7806; and

Ex. 336 (Letter from Dr. Blajchman to Dr. Perrault, dated August 28, 1990).

⁸⁶³ *Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8614-8615; and*

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27562-27563.

(as well as Australia and the United States) asked such questions of donors in 1983.⁸⁶⁴ The CRCS was aware of this practice and deliberately departed from this course of action.⁸⁶⁵

505. On January 13, 1983 the American volunteer blood banks issued a *Joint Statement on AIDS Related to Transfusion*⁸⁶⁶, which suggested seven measures to limit blood donations from individuals at high risk for AIDS, including asking all donors about AIDS-related symptoms. This Joint Statement was reviewed at the CRCS Immunology/Virology Working Group Meeting of January 21, 1983, where it was deemed to be a sound guide to CRCS policy on the AIDS issue, but was to be examined further for its applicability to the Canadian situation.⁸⁶⁷ Dr. Davey sent this Joint Statement to all Medical Directors and asked that they endorse it as *working policy until* a full meeting of the Medical Directors could be convened to discuss the CRCS response to AIDS.⁸⁶⁸ He reported back to them on February 10, 1983 that all Medical Directors had endorsed the Joint Statement as working policy pending the Medical Directors meeting on March 23 to 24, 1983.⁸⁶⁹ In the interim, the March 10, 1983 Press Release was issued advising that such questions would be asked of donors.

506. The CRCS was concerned about the implications of telling donors that they were deferred as a result of a positive response to AIDS symptom-specific questions, particularly at a time when there were conflicting theories and tremendous hysteria about AIDS. Deferring such donors could have made donors unnecessarily fearful,⁸⁷⁰ since there was, as yet, no

⁸⁶⁴ Ex. 715, Vol. 155 (*International Overview of Donor Screening Measures Introduced in 1983*).

⁸⁶⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28473-28476; and
Ex. 618, CRC Vol. 15, Tab 1 (1983 CRCS Donor Questionnaire).

⁸⁶⁶ Ex. 616, CRC Vol. 13, Tab 9 (*Joint Statement on AIDS Related to Transfusion*, dated January 13, 1983).

⁸⁶⁷ Ibid, Tab 18 (*Minutes, Immunology/Virology Working Group Meeting*, dated January 21, 1983, paragraph 28).

⁸⁶⁸ Ex. 660, CRC Vol. 57, Tab 25 (*Memo from Dr. Davey to all Medical Directors*, dated January 24, 1983).

⁸⁶⁹ Ex. 616, CRC Vol. 13, Tab 29 (*Memo from Dr. Davey to all Medical Directors*, dated February 10, 1983).

⁸⁷⁰ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27606-27607.

confirmatory test to provide reassurance to a deferred donor. Because of the non-specificity of the symptom-specific questions, it was clear that many donors would have been deferred for AIDS symptoms when they had only relatively minor health conditions.⁸⁷¹ At that time, it was believed unlikely that persons with AIDS could classify themselves as healthy. Finally, the staff at the CRCS blood donor clinics were not trained to make diagnoses:

...Now, if one reflected then on what the, you know, the utility of these, what could result from positive answers.

First, we didn't expect individuals with AIDS to be coming to our clinics as blood donors, and if they did then, given the severity of their condition, they would be disqualified simply by reason of their health, without going any further.

And, second, so that this -- we weren't, as I said, providing a diagnostic service.

And then as to all the other questions -- the questions, as I said are very non-specific. Given that AIDS itself is a low prevalence condition, very low prevalence, most of the answers to these would be in -- if we used the testing terms, which are quite applicable, would be, non-specific, and in terms of detecting AIDS or anything related to it, false positive.

The largest proportion of people answering yes to any of those questions would not have AIDS and AIDS prodrome or anything like it.⁸⁷²

507. Therefore, the CRCS chose the "good health approach" as opposed to asking symptom-specific questions:

Now, something I felt that we should avoid, and this I felt very strongly, was applying this sort of screening process and having people leave our clinics believing that they had AIDS or a significant risk of developing AIDS.

⁸⁷¹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27585-27593;

Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41911-41913;

Ex. 811, Vol. 182, Part I, Tab 5 (*Hemophilia Newsnotes*, 1980); and

Ex. 812, Vol. 182, Part II, Tab 1 (*Hemophilia Information Exchange*, March 1985).

⁸⁷² Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27585-27593.

And it was in light of this that I went on to say, "Let's concentrate on the health of individuals." If anyone is not healthy, is not well at the time they present to our clinics, whatever is wrong with them, they should not give blood.

Now, after, if the answer to that question: "Are you well," is "No," then the nurse, at discretion, can go on and ask whatever questions are necessary to advise the patient -- the person, I should say, not patient but donor, what they might do. But those nurses aren't in a position to offer a tentative diagnosis. All they need to say is: "Look, if you are not well today, please, don't give blood."⁸⁷³

508. Dr. Davey made his views in favour of the "good health approach" known at the Medical Directors Meeting of March 24 to 25, 1983. The discussion is minuted as follows:

One Medical Director has included the question: "Have you had any unexplained night sweats, swollen glands, etc.?" on the bottom of the Donor Questionnaire. The general consensus of the group was that such a question would be acceptable. Any questions added to this questionnaire should be short and general, rather than detailed. Dr. Davey further suggested that no Centre should be asking any questions other than the basic: "Are you well?" and most definitely, no Centre should be conducting its own diagnostic quiz for A.I.D.S...⁸⁷⁴ (Emphasis added.)

509. Dr. Davey's words at this Medical Directors meeting must be considered as part of the discussion, rather than as a direction. Although the minutes indicate a consensus among the attendees at the Medical Directors meeting that a question about AIDS symptoms "would be acceptable", this issue was not discussed fully. Nor was a decision rendered at that meeting. The issue was specifically put over to be dealt with by the *Ad Hoc* Working Group on AIDS, which met only a few days later, on March 29, 1983.⁸⁷⁵

510. After a full review of the issue and discussion by the members of the *Ad Hoc* Working Group on AIDS, the "good health approach" was supported. The members of the Working Group who attended were Dr. Perrault, Dr. Derrick, Dr. Guevin, Ms Bart, Ms Lark,

⁸⁷³ *Ibid*, p. 27587.

⁸⁷⁴ Ex. 617, CRC Vol. 14, Tab 16 (*Minutes of Medical Director Committee Meeting, dated March 24-25, 1983, Paragraph 75(h))*.

⁸⁷⁵ *Evidence of Dr. Bowen, Calgary Centre Medical Director, pp. 7731-7734.*

Dr. Rock, and Dr. Rousseau. Invited guests were Dr. Decary, Dr. Leclerc-Chevalier (from the CBC), Ms Gauthier (National BDR), Ms Lefevre (Quebec PR), Mr. Worsoff (counsel), and Dr. Sternbach. Dr. Davey was not present at that meeting; any suggestion that the Working Group simply adopted his approach is not borne out by the evidence. It was determined that AIDS symptoms were too specific and general. The "good health approach" was believed to be equally effective in screening out donors with AIDS symptoms and would not cause alarm when donors not at risk for AIDS were deferred, as inevitably would happen.⁸⁷⁶ While the March 10, 1983 press release announced that the CRCS would be asking symptom-specific questions, that position was changed after the issue was considered at the March Medical Directors meeting, and fully aired by a committee struck for the purpose of considering it, with the result that the decision was communicated to all Medical Directors.⁸⁷⁷

511. The decision not to institute AIDS symptom-specific questions was also endorsed by the BTS Advisory Committee, at its April 15, 1983 meeting.⁸⁷⁸ Significant technical or scientific operational issues were always referred by the Medical Directors committee to the BTS Advisory Committee, which met twice a year. The members of the BTS Advisory Committee were volunteers specifically chosen for their expertise in the medical, technical and scientific aspects of blood transfusion.⁸⁷⁹ For example, from 1983 to 1985, Dr. Barker or Dr. Katz represented Amcross, Drs. Whittemore, Matthews, Bienenstock and other physicians had expertise in blood-related matters, Messrs. Kerr and Paterson represented the Board of Directors, and Mr. Worsoff attended as CRCS counsel. Ex-officio members included the President of the Society, George Weber, Drs. Perrault and Davey, and two Medical Directors.

⁸⁷⁶ Ex. 617, CRC Vol. 14, Tab 20 (*Minutes of Meeting of the Ad Hoc Working Group on AIDS*, dated March 29, 1983).

⁸⁷⁷ Ex. 617, CRC Vol. 14, Tab 3 (*CRCS Press Release*, dated March 10, 1983).

⁸⁷⁸ Ex. 618, CRC Vol. 15, Tab 12 (*Minutes of the BTS Advisory Committee meeting*, dated April 15, 1983).

⁸⁷⁹ Evidence of Christopher Patterson and Lin Good, *Board of Governors Panel*, pp. 40079-40081; and Evidence of George Weber, *former Secretary General*, pp. 40541-40543 and 40557.

Dr. Clayton and Dr. Chevalier attended as guests and BTS, BTR, and PR staff members were always present. Minutes of the meetings were circulated widely throughout the BTS.⁸⁸⁰

512. Those present at the BTS Advisory Committee meeting to consider the "good health approach" were Dr. Matthews, Mr. Balfour, Dr. Barker (AmCross), Dr. Bienenstock, Dr. Boyd, Dr. Ingram, Mr. Kerr, Dr. Smiley, Dr. Whittemore, Mr. Worsoff, Dr. Zanir, and Dr. Perrault. Ex-officio attendees were Mr. Thompson (National BDR), Dr. Davey, Dr. Gorelick, Dr. Guevin, Dr. Moore (N.R.L.), and Mr. Morin. Dr. Leclerc-Chevalier, Dr. Clayton and Dr. Painter were guests. Staff members who attended were Ms Bart, Dr. Derrick, Ms Humphreys, Ms Kelner, Dr. Krassnitzky, Ms Lark, Ms Levine, Mr. Morgan, Dr. Naylor, and Mr. Rea.

513. As always, two Medical Director representatives were present (Dr. Gorelick and Dr. Guevin). The practice of the Medical Director representatives was to canvass the opinions of their colleagues prior to BTS Advisory Committee meetings so that they had an opportunity for input. Neither Dr. Gorelick nor Guevin objected.⁸⁸¹ Nor did the BoB object to CRCS donor screening measures when it inspected CRCS plasmapheresis operations.⁸⁸² Nor did Dr. Clayton of LCDC and NAC AIDS or Dr. Leclerc-Chevalier, who attended as guests to every

⁸⁸⁰ Evidence of Bob Hemming, Board of Governors Panel, p. 40066.

Ex. 618, CRC Vol. 15, Tab 12 (Minutes of BTS Advisory Committee Meeting, dated April 15, 1983);

Ex. 623, CRC Vol. 20, Tab 1 (Minutes of BTS Advisory Committee Meeting, dated November 18, 1983);

Ex. 627, CRC Vol. 23, Tab 20 (Minutes of BTS Advisory Committee Meeting, dated April 26, 1984);

Ex. 629, CRC Vol. 26, Tab 27 (Minutes of BTS Advisory Committee Meeting, dated November 2, 1984);

Ex. 634, CRC Vol. 31, Tab 27 (Minutes of BTS Advisory Committee Meeting, dated April 26, 1985); and

Ex. 640, CRC Vol. 37, Tab 7 (Minutes of BTS Advisory Committee Meeting, dated November 1, 1985).

⁸⁸¹ Evidence of Dr. Perrault, former National Director BTS, and Dr. Davey, former Assistant National Director BTS, pp. 27681-27683.

⁸⁸² Evidence of Dr. Boucher, BoB Panel, pp. 42763-42764.

BTS Advisory Committee meeting, ever voice any objections.⁸⁸³ In fact, Dr. Clayton testified as follows:

I think the majority of people who would have -- who were caught up in that widely cast net would have been not appropriate, even if you included fevers and night sweats and other things, and weight loss and so forth, the net would be cast too wide and the mesh would be too narrow.⁸⁸⁴

514. It was believed that the principle behind the statement of intent in the press release (to weed out donors with symptoms of AIDS) was implemented equally effectively by this approach, since any donor who was unwell, regardless of the reason, would be deferred from donation.⁸⁸⁵ Later, at an American Blood Commission Board of Directors Meeting on December 14, 1983, Dr. Bruce Evatt agreed that donors with AIDS would likely be too ill to donate.⁸⁸⁶

515. While no public announcement was made about the change from the procedure described in the March 10, 1983 press release, nor was NAC AIDS *formally* advised, the decision had been made by those most concerned and knowledgeable about donor screening and

⁸⁸³ Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41610-41613, 41620-41622, 41823-41825, 41914-41924.

Ex. 683, Vol. 147, Tab 16 (NAC AIDS Minutes, dated November 9, 1983, at p. 3);

Ex. 680, Vol. 144, Tab 35 (Letter from Dr. Jessamine to NAC AIDS members, dated Jan 3, 1984); and

Ex. 680, Vol. 144, Tab 32 (Letter from Dr. Perrault to Dr. Clayton, dated November 14, 1983)..

⁸⁸⁴ Evidence of Dr. Clayton, NAC AIDS Panel, p. 41913.

⁸⁸⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27642-27644, 27447-27448;

Evidence of Dr. Schroeder, Medical Director Winnipeg BTS Centre, pp. 9777-9778;

Evidence of Dr. Fast, Manitoba Health Authorities Panel, pp. 10589-10590; and

Evidence of Dr. Shepherd, NAC AIDS Panel, p. 25347;

Evidence of Dr. Perrault, former National Director BTS, pp. 27513-27515, 27630-27631.

⁸⁸⁶ Ex. 556, Vol. 129, Tab 71, (American Blood Commission "Status of AIDS and Transfusion" by Bruce Evatt, dated December 14, 1983, p. 0293).

the blood supply and was known to NAC AIDS, the CBC and LCDC.⁸⁸⁷ The "good health approach" was implemented openly at all the seventeen blood centres and mobile clinics across the country. The suggestion that the decision was made and the practice followed in some secretive way to avoid public scrutiny must be rejected.

516. The procedure followed in the voluntary blood banks in the United States was not dissimilar to that in Canada. Even after the AABB, CCBC, AmCross *Joint Statement on AIDS Related to Transfusion* dated January 13, 1983 was issued recommending that donor screening include specific questions designed to detect possible AIDS or exposure to patients with AIDS⁸⁸⁸, very few American blood banks asked symptom-specific questions of every donor. AmCross decided to use the non-threatening, non-challenging question that had been asked of donors for years: "Are you well?" Only if a donor answered that question in the negative, did the nurse have discretion to ask the donor AIDS symptom-specific questions. Therefore, if a donor answered that he or she felt well, the nurse was not required to ask the donor about symptoms of AIDS.⁸⁸⁹ Also, at a BPAC Meeting of July 19, 1983 it was agreed that recall of a donation by an individual who later exhibited signs or symptoms of AIDS was not justified.⁸⁹⁰

517. Many questions which could target AIDS symptoms or high-risk individuals, were already covered in the CRCS Donor Questionnaire as evidence of poor health, such as drug abuse (injections), Kaposi's sarcoma (malignancy, skin problems), cold, visit to malarial area (recent immigrant from Haiti), hepatitis, sore throat, flu, and chronic health problem or serious

⁸⁸⁷ As stated above Drs. Clayton and Leclerc-Chevalier were in attendance at the BTS Advisory Committee meeting.

⁸⁸⁸ Ex. 554, Vol. 128, Part I, Tab 18 (*Joint Statement on AIDS Related to Transfusion*, dated January 13, 1983).

⁸⁸⁹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22380-22381, 22394-22395.

⁸⁹⁰ Ex. 566, Vol. 138, Tab 4 (*Minutes of BPAC Meeting*, dated July 19, 1983 at p. 3).

illness.⁸⁹¹ It was believed that the question as to injections would alert past users intravenous drugs to speak to a clinic nurse. The March 10, 1983 press release referred to both past and present I.V. drug abusers at high risk for AIDS.⁸⁹² Clinic nurses were also trained to look for track marks. AIDS through I.V. drug use was a very minor problem in Canada.⁸⁹³

518. This issue of appropriate donor screening measures cannot be viewed in isolation. It must be considered in conjunction with the degree of risk understood in Canada, the desire for consensus and involvement of the Medical Directors and other staff, the potential impact on the donor population, and the financial resources available to the CRCS for manpower and private facilities to conduct such questioning. The introduction of such donor screening devices was unprecedented in Canada. While in retrospect it might seem that the concerns were not substantial, given the risk as it is now understood, one must consider the issue from the perspective at that time.

519. To date there have been no studies directly demonstrating the effectiveness (or ineffectiveness) of symptom-specific questions in weeding out donors at high risk for AIDS.⁸⁹⁴

⁸⁹¹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27422-27423;

Evidence of Dr. Perrault, former National Director BTS, pp. 27630-27631, 27642-27644; and

Ex. 618, CRC Vol. 15, Tab 1 (1983 CRCS Donor Questionnaire).

⁸⁹² Ex. 617, CRC Vol. 14, Tab 3 (CRCS Press Release dated March 10, 1983).

⁸⁹³ As of March 1985, only one case had been reported as opposed to over one thousand cases in the U.S. Nevertheless, a specific question about past I.V. drug use was placed in the January 1986 CRCS donor screening pamphlet. By that time more was known about the incubation period and testing for anti-HIV was available. The social climate in Canada had changed markedly since 1983, enabling questions about donor symptoms of AIDS and high-risk behaviour.

Ex. 1001, Vol. 247, tab 21 (CDWR dated March 1985).

Ex. 642, CRC Vol. 39, Tab 3 (CRCS Pamphlet, "AIDS New Information for All Blood Donors", dated January 1986).

⁸⁹⁴ Evidence of Dr. Perrault, former National Director BTS, p. 27731

But one must consider the evidence of both Dr. Davey and Dr. Remis comparing the TAA cases with those countries that instituted such screening devices. A discussion of this follows.

Some evidence from the Greater New York Blood Program (GNYBP) showed that asking such questions could increase the deferral rate significantly. However, at the GNYBP, there was an increased number of deferrals for chronic and persistent cough, the very symptom about which clinic nurses had received the most training.⁸⁹⁵ Other data from AmCross indicated that such questions had absolutely no effect on the deferral rate.⁸⁹⁶ Indeed, Dr. Mathias testified at the Inquiry that the 'good health' question asked by the CRCS is still "the best screening question that anybody has ever devised for separating people who are well from people who are not well."⁸⁹⁷

520. It is important to note that countries such as Australia and Belgium, which utilized symptom-specific questions, had no significant difference in the national incidence of AIDS but had a *higher* incidence of TAA than Canada. France, which also used symptom-specific questions, had both a significantly higher incidence of AIDS than Canada and a significantly higher incidence of TAA. The U.K., which did not implement symptom-specific questions in 1983, had a lower incidence of AIDS than Canada and had one of the lowest rates of TAA.

521. This evidence discloses that asking such questions had little effect on the ultimate safety of the blood supply.⁸⁹⁸ A comparison and analysis of the incidence of TAA, AIDS due

⁸⁹⁵ Ex. 555, Vol. 128, Part II, Tab 33 (CCBC Newsletter, dated September 9, 1983).

⁸⁹⁶ Ex. 680, Vol. 144, Tab 3 (Memo from Dr. Derrick to all Medical Directors, dated June 2, 1983); and Evidence of Dr. Perrault, former National Director BTS, pp. 27725-27731.

⁸⁹⁷ Evidence of Dr. Mathias, NAC AIDS Panel, p. 24728.

⁸⁹⁸ Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey);

Ex. 1028, Tab 7 (Comparative Analysis of AIDS Incidence, Total and Associated with Clotting Factors and Transfusion, cumulative to March 1995 for selected countries in North America, Europe and Oceania, dated August 11, 1995, by Dr. Remis);

Ex. 1278 "An International Comparison of the Incidence of AIDS Associated with Blood and Blood Products," Abstract of Poster Presentation by Martin Davey from the annual meeting of the Canadian Society for Transfusion Medicine, 24-26 May 1996;

Ex. 1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4:

to component therapy, and AIDS in general in North America and Europe demonstrates that Canada did as well, or better, than countries which utilized symptom-specific questions. An analysis of this data is found in this section.

7) Implementation of CRCS Donor Screening Pamphlets

a) Overview

522. The following summary of information to donors regarding AIDS, and high-risk groups and activities demonstrates the evolution of the CRCS donor screening pamphlets to November 1986:

- Donor Questionnaire (1983)⁸⁹⁹:
 - augmented preamble emphasizes importance of good health
 - no AIDS questions
 - no AIDS symptoms
 - no discussion of AIDS
- *An Important Message to Our Blood Donors* (April 1984)⁹⁰⁰
 - discusses AIDS
 - no AIDS symptoms
 - Lists high-risk groups as:
 - homosexual or bisexual males who have *multiple partners*;

Ex. 1039 (Remis data, dated October 12, 1995, titled "Comparative Analysis of rates of AIDS including AIDS associated with transfusion and clotting factors among 20 countries of Western Europe (including all countries with populations greater than million), North America and Australia, December 1994-April 1995); and

Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41929-41930.

⁸⁹⁹ Ex. 618, CRC Vol. 15, Tab 1 (CRC BTS Donor Questionnaire, dated April 1983).

⁹⁰⁰ Ex. 626, CRC Vol. 23, Tab 13 ("Important Message To Our Blood Donors", dated April 1984).

- recent immigrants from, or visitors to, those areas where AIDS is endemic i.e. Haiti, Zaire, Chad;
 - present or past abusers of intravenous drugs;
 - sexual partners of any of the above persons;
 - interview with nurse only if positive response to health questions
- *An Important Message to Our Blood Donors - AIDS (August 1985)*⁹⁰¹
 - Lists high-risk groups as:
 - active homosexual and bisexual males;
 - any person who has shared a needle to inject drugs;
 - any man or woman who has had sexual relations with someone other than his or her usual partner, particularly with a prostitute, in areas where AIDS cases are known to occur, especially Central Africa, Haiti and major North American cities; and
 - sexual partners of any of these people
 - hemophiliacs are more susceptible to AIDS because they regularly need blood products and these are obtained from the plasma of many donors
 - *AIDS, New Information for All Blood Donors (January 1986)*⁹⁰²
 - Lists high-risk groups as:
 - any male who has had sex with another male since 1977;
 - any person who has ever taken illegal drugs by needle;
 - any person who has regularly received treatment with blood products; and
 - sexual partners of any of these people
 - lists AIDS symptoms

⁹⁰¹ Ex. 637, CRC Vol. 34, Tab 20 (*AIDS An Important Message to Our Blood Donors*, dated August 1985).

⁹⁰² Ex. 642, CRC Vol. 39, Tab 3 (CRCS Pamphlet, "AIDS New Information for All Blood Donors", dated January 1986).

- if a donor has been to any area where there are many AIDS cases, such as Central Africa, Haiti, and the following areas of North America - New York, San Francisco, Miami, and Los Angeles - talk to nurse to see if it is safe to donate
- *AIDS, New Information for All Blood Donors* (Revised May, 1986)⁹⁰³
 - Lists high-risk groups as:
 - any male who has had sexual relations with another male since 1977;
 - any person who has shared a needle to inject drugs;
 - any person who has regularly received treatment with blood products;
 - men and women who have had sexual relations with different partners in areas where AIDS cases are known to occur, such as Central Africa, Haiti and major North American cities; and
 - sexual partners of any of these people
 - lists AIDS signs and symptoms
- *AIDS, New Information for All Blood Donors* (Revised, November 1986)⁹⁰⁴
 - Lists high-risk groups as:
 - any male who has had sexual relations with another male since 1977;
 - any person who has shared a needle to inject drugs;
 - any person who has regularly received treatment with blood products;
 - any man or woman who has had sexual relations with someone other than his or her usually partner, particularly with a prostitute, in areas where AIDS cases are known to occur especially Central Africa, Haiti and major North American cities; and
 - sexual partners of any of these people

⁹⁰³ Ex. 644, CRC Vol. 41, Tab 29 ("AIDS - New Information for All Blood Donors", dated May 1986).

⁹⁰⁴ Ex. 647, CRC Vol. 44, Tab 14 ("AIDS New Information for All Donors", dated November 1986).

b) AIDS Pamphlet

523. There has been criticism that the time it took for the CRCS to implement its first AIDS pamphlet was unnecessarily long. The CRCS had other deferral measures in effect in the meantime, which it believed were working. The message of self-exclusion was believed to be getting out to high-risk donors by the media and direct contact with the high-risk communities. The pamphlet was considered to be an additional safeguard to what was believed to be an already effective strategy.⁹⁰⁵

524. Following suggestions by Dr. Davey and Dr. Herst in the summer of 1983, the meeting of the *Ad Hoc Working Group on AIDS* on September 13, 1983 determined that the BTS would start the process of developing an AIDS information pamphlet for use at clinics.⁹⁰⁶ The pamphlet was to be reviewed by internal personnel at BTS, BDR and Public Relations (PR). This decision to prepare a pamphlet was approved by the BTS Advisory Committee at its November 18, 1983 meeting.⁹⁰⁷ The pamphlet was drafted and circulated for review in December 1983 and again in the spring of 1984.⁹⁰⁸ It was sent for translation into French, presented to the Medical Directors and approved at the March 29 to 30, 1984 Medical Director's Committee meeting.⁹⁰⁹ The final version of the pamphlet was forwarded to all Medical Directors on April 16, 1984 with instructions that it be fully implemented at every centre on May 1, 1984.⁹¹⁰

⁹⁰⁵ Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40623-40628

⁹⁰⁶ Ex. 621, CRC Vol. 18, Tab 19 (Minutes of Ad Hoc AIDS Working Group, dated September 13, 1983).

⁹⁰⁷ Ex. 623, CRC Vol. 20, Tab 1 (Minutes of BTS Advisory Committee Meeting, dated November 18, 1983).

⁹⁰⁸ Ex. 624, CRC Vol. 21, Tab 20 (Memo from Dr. Derrick to Dr. Gorelick, dated February 14, 1984 enclosing draft pamphlet).

⁹⁰⁹ Ex. 625, CRC Vol. 22, Tab 21 (Minutes of Medical Directors Committee Meeting, dated March 29-30, 1984).

⁹¹⁰ Ex. 626, CRC Vol. 23, Tab 13 (Memo from Mary Ann Lark to Medical Directors, re: Implementation of AIDS Pamphlet, dated April 16, 1984, enclosing CRCS Pamphlet, "An Important Message to Our Blood Donors").

525. By way of comparison, the Health and Welfare Canada pamphlet entitled *AIDS: What You Should Know* took essentially the same amount of time to produce and distribute. The first discussions about disseminating AIDS information to all medical associations occurred at the November 9, 1983 NAC AIDS meeting.⁹¹¹ The Communications Sub-Committee was delegated the task of drafting this pamphlet. The pamphlet was circulated to all physicians in the spring of 1984.⁹¹²

526. Similarly, Dr. Mary Fanning, then the Chair of PAC AIDS, testified that the PAC AIDS pamphlet called, *Understanding AIDS*, which was circulated to doctors, clinics, hospitals and laboratories was reviewed by her in draft form in November and December 1983. It was ultimately mailed out in March 1984.⁹¹³

527. The comparison between the time it took to implement the CRCS pamphlet, as opposed to the NAC AIDS and PAC AIDS pamphlets, shows that the CRCS action was in keeping with the time frames for such material (and ultimate risk evaluation) of the day.

8) Staff Members Were Instructed that Donors Must Read the Donor Questionnaire

528. Prior to the introduction of the first AIDS pamphlet in 1984, the technician performing the hemoglobin tests asked prospective donors if they were feeling well. Following

⁹¹¹ Ex. 683, Vol. 147, Tab 16, p. 10 (*Minutes of NAC AIDS meeting, dated November 9, 1983*).

⁹¹² Ex. 680, Vol. 144, Tab 56, p. 196 (*Health and Welfare pamphlet, "AIDS: What You Should Know", dated 1984*); and

Evidence of Dr. Gilmore, former member of NAC AIDS, pp. 22480-22812.

⁹¹³ *Evidence of Dr. Fanning, former Chair of PAC AIDS, pp. 2114-2122 .*

the introduction of the AIDS pamphlet, it was National protocol that the technician was to ensure that every donor had both read and understood the Donor Questionnaire.⁹¹⁴

529. An "Aspirin Study" was conducted by Fran Brisson, Nursing Supervisor at the Ottawa Centre, in January 1984, to determine if donors were reading the health questionnaire. Donors were provided with the 1983 national Donor Questionnaire, which asked them to advise a nurse if they had taken medication for headache within the *last 24 hours*. Donors who participated in this study were then asked a series of three questions orally by the clinic technician:

- Have you read the questionnaire today?
- Is there anything you need to discuss?
- Have you taken anything containing aspirin *in the last 3 days*?

530. The study disclosed that many donors did not advise, until they were specifically asked, that they had consumed aspirin within the last *three* days.⁹¹⁵ One conclusion drawn was that donors were not reading the Donor Questionnaire. Dr. Rock forwarded the results of this study to Mary Ann Lark, National Director of Nursing, as a warning. Ms. Lark responded with the assurance that special emphasis would be placed upon the need for donors to read the pamphlet prior to donating. As Dr. Davey testified, the conclusion that donors were not reading the pamphlet, did not necessarily follow as the study was flawed. The national Donor Questionnaire asked a donor to indicate to a nurse if he or she had consumed aspirin within the last 24 hours, *not* with the last three days (or 72 hours). Consequently, donors had no reason to volunteer information that they had consumed aspirin more than 24 hours but less than three days before their donation, unless specifically asked. Nonetheless, National Office continued

⁹¹⁴ Ex. 743, Tab 1 (*Excerpt from 1984 Nursing Procedure Manual*); and

Ex. 623, Vol. 20, Tab 1 (*Appendix VI to Minutes of BTS Advisory Committee dated November 18, 1983*).

⁹¹⁵ Ex. 623, CRC Vol. 20, Tab 32 (*Memo from F. Brisson to Dr. Rock re: Nursing Comments on "The Position of the CRC BTS with reference to the AIDS Problem and Donor Screening", dated January 5, 1984*).

to emphasize to centres that full reading of the pamphlet by donors was absolutely essential for the donor screening program.⁹¹⁶

531. Medical Directors across the country testified that clinic staff were told that pamphlets were to be used at all times. They further testified that there were always sufficient supplies of pamphlets at their centres, and that their centres never ran out of pamphlets, even if that meant recycling or utilizing laminated pamphlets. Because pamphlets were recycled, the initial three-month supply was sufficient for Centre requirements. Many Medical Directors testified adamantly that Mary Ann Lark's memo of January 9, 1985 and Ron Rea's memo of December 19, 1984 (indicating that some centres were not using the pamphlet or had run out of the pamphlet) were incorrect. Neither Mary Ann Lark nor Ron Rea were called to testify about these memoranda.⁹¹⁷

⁹¹⁶ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28350-28359.

⁹¹⁷ Evidence of Dr. Alport, Regina Centre Medical Director, pp. 8946-8947;

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8946-8947;

Ex. 631, CRC Vol. 28, Tab 13 (Memo from Ron Rea to Advisor, Regulatory Affairs and Good Manufacturing Practises, BTS, c.c. to Mary Ann Larke, dated December 19, 1984);

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28350-28359;

Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20516, 21065, 21417-21418;

Ex. 520 (Memo from Janet Wells, CRCS to Linda Larmour re: Important Message to Our Blood Donor Pamphlet, dated February 27, 1985);

Ex. 521 (Memo from Elizabeth Muir, CRCS to Jane Buchan, dated April 18, 1985);

Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13958-13963, 14082;

Evidence of Dr. Guevin, former Montreal Centre Medical Director, pp. 15735-15736, 15743;

Evidence of Dr. MacKay, Saint John Centre Medical Director, p. 11828-11829;

Ex. 631, CRC Vol. 28, Tab 27 (Memo from Mary Ann Larke to Dr. Davey, dated January 9, 1985); and

Evidence of Vincent Leroy Veinotte, former Director of the Blood Donor Recruitment Division for the CRCS New Brunswick, pp. 49076-49140.

9) Evolving Appreciation of Risk and The Definition of "Multiple Partners"

532. Early epidemiological data suggested that those members of the gay community at greatest risk for AIDS were those who had a multitude of sexual partners. Blood bankers struggled with an appropriate definition in the absence of scientific data. Not enough was known about the mode or the risk of transmission of AIDS to be able to better define the threshold number of partners which might constitute "high risk".

533. The CDC high-risk group definition in March 1983 was: "sexually active homosexual or bisexual men with multiple partners".⁹¹⁸ Despite the fact that the CDC definition was universally accepted, blood bankers around the world were struggling with this definition. They recognized its ambiguity but they did not have sufficient epidemiological data to better define the extent of the risk among gay and bisexual men.⁹¹⁹ There were reports in San Francisco of affected gay men having thousands of partners. By that definition, Dr. Randy Coates, an epidemiologist and AIDS researcher, believed that gay men in Toronto were less at risk because they did not have as many partners and were therefore not "promiscuous".⁹²⁰ In January 1983, Dr. Francis proposed the following definition in an internal CDC memorandum:

...sexually (heterosexual or homosexual) promiscuous (more than an average of 2 different people per month for the previous 2 years)".

⁹¹⁸ Ex. 554, Vol. 128, Part I, Tab 54 (HHS News Release, dated March 4, 1983);

Ex. 616, CRC Vol. 13, Tab 43 (AmCross News Release, dated March 4, 1983);

Ex. 550, Vol. 125, Part I, Tab 27 (MMWR, dated March 4, 1983);

Ex. 617, CRC Vol. 14, Tab 3 (CRCS Press Release, dated March 10, 1983); and

Ex. 617, CRC Vol. 14, Tab 15 (FDA Recommendations, dated March 24, 1983 re: *Recommendations to Decrease the Risk of Transmitting AIDS from Blood Donors*).

⁹¹⁹ Ex. 715, Vol. 155 (International Overview of Donor Screening Measures introduced in 1983).

⁹²⁰ Evidence of William Mindell, CHS Member (Ontario Chapter) pp. 32196-32197.

He arbitrarily set the threshold at more than 48 partners in the previous two years.²¹ During his testimony, Dr. Francis admitted that this definition was somewhat impractical because it required very detailed questioning but, given the state of knowledge, it was an attempt to provide more information about the requisite number of sexual contacts and, equally importantly, to deal with gay civil rights issues. It was clear that the gay community would consider a blanket exclusion of all gay men to be discriminatory.²²

534. The confusion about multiple partners was evident in the answers to questions 1 and 17 drafted by Drs. Derrick, Perrault and Davey of the *Potential Media Questions Concerning AIDS* which had been drafted by Bill Mindell of the Toronto Board of Health. The answers to questions 1 and 17 were used by Dr. Herst at the July 19, 1983 Press Conference to announce the formation of the AIDS Committee of Toronto (ACT):

Question 1: Are Haitians and male homosexuals allowed to give blood?

Answer: Haitians and male homosexuals are allowed to donate blood in Canada provided they meet the selection criteria required of all blood donors. However, because of the uncertainties surrounding this issue, certain members of these two groups who are considered to be at high risk of developing AIDS, namely Haitians who are recent immigrants and male homosexuals (or bisexuals) having multiple sex partners are being advised not to become blood donors at this time.

Question 17: You have advised against promiscuous homosexuals and bisexual males giving blood, what's your definition of promiscuous? How many partners should a homosexual have had before he should exclude himself from donating blood? And in what time period?

Answer: The degree of promiscuity has ceased to be a factor since cases are now known where a single intimate contact has resulted in AIDS development. Until more is known, individuals belonging to groups at higher than normal risk of developing AIDS are advised to refrain from donating blood.²³ (Emphasis added)

²¹ Ex. 554, Vol. 128, Tab 5 (Memorandum from Dr. Francis to Dr. Kaplan, dated January 6, 1983).

²² Evidence of Dr. Francis, former Epidemiologist, CDC, pp. 21847-21849, 21920-21921, 22124-22126.

²³ Ex. 620, CRC Vol. 18, Tab 15 (Memo from Dr. Derrick to Medical Directors, dated July 25, 1983, attaching Potential Media Questions Concerning AIDS).

535. Dr. Herst testified as to the meaning of answers 1 and 17. Promiscuity had ceased to be a factor for risk since one sexual contact with an infected person could expose one to the putative agent causing AIDS. However, those at *high* risk were still those with multiple sexual partners; the greater the number of partners, the greater the risk.⁹²⁴

536. Therefore, promiscuity was still a factor but the threshold as to number of partners which put one at risk was lower than it was believed previously. Nonetheless, those at high-risk were still those with "multiple partners". There was not yet sufficient data to say that multiple meant "more than one".⁹²⁵ In response to criticism by the gay community, the CRCS reiterated this position in its July 22, 1983 press release, to make it clear to the community that only those with "multiple partners", and not all members of the gay community, should refrain from donating.⁹²⁶

537. The definition used by the CRCS was also the one widely used by other blood banks at the time. One exception was the Irwin Memorial Blood Bank which, in July 1983, defined "multiple" as "more than one". It is significant however, that the Irwin Memorial Blood Bank is located in San Francisco, one of the highest risk areas in the United States.⁹²⁷ A CDC internal memorandum from Dr. Curran in November 1983 conceded that "multiple partners" was a confusing term but stated that there was not sufficient information to better articulate the high-risk number of partners or the high-risk geographical areas.⁹²⁸ This spectrum of definitions of multiple partners in 1983 documents the uncertainty of the time and the lack of scientific data. New evidence was necessary in order to avoid inflaming the gay community.

⁹²⁴ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20413-20414.

⁹²⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28241-28245.

⁹²⁶ Ex. 620, CRC Vol. 17, Tab 10 (CRCS Press Release, dated July 22, 1983).

⁹²⁷ Ex. 555, Vol. 128, Part II, Tab 19 (Memo from Dr. Perkins to all Physicians and Nurses - Irwin Memorial Blood Bank, dated July 12, 1983).

⁹²⁸ Ex. 562, Tab 29 (Letter from Dr. Curran to Virginia Apusso, dated November 18, 1983).

538. It was not until 1984 that there was a gradual awareness of the problem with the definition of multiple partners. In January 1984, the American Red Cross implemented a pamphlet which included the following definition: "sexually active homosexual or bisexual men with multiple partners (more than one)."⁹²⁹ It was not until December 1984, that the Food and Drug Administration ("FDA") changed its definition to "any male who has had sex with another male since 1979".⁹³⁰

539. If a donor was uncertain as to the definition of "multiple partners" or "active homosexual or bisexual" in the 1984 or 1985 CRCS pamphlets, the donor was specifically encouraged to discuss this with a nurse, who would provide more information.⁹³¹ There was evidence that people in the gay community understood the message, acted responsibly, and refrained from donation if there was any possibility that they might fit into the high-risk category:

I think that people who were well educated and well informed would have interpreted it that way. Actual, you know, what the word "multiple" means really is more than one. I'm -- I think that the trouble with it is that it's language that uses big words and that there are people out there who might not understand it. But yes, certainly well educated, well informed people interpreted it that way...⁹³²

540. The knowledge about the risk of transmission and the sexual practices of the gay community gradually evolved throughout the 1980s, as did the social climate with respect to asking questions about sexual activities. During this period, the sensibilities of the community

⁹²⁹ Ex. 556, Vol. 129, Tab 1 (*AmCross pamphlet, dated January 1984*).

⁹³⁰ *Ibid, Tab 70 (FDA Recommendations, dated December 14, 1984 re: Revised Recommendations to Decrease the Risk of Transmitting AIDS from Blood and Plasma Donors)*.

⁹³¹ Ex. 626, CRC Vol. 23, Tab 13 (*Memo from Mary Ann Lark to all Medical Directors re: Implementation of AIDS Pamphlet, dated April 16, 1984, enclosing the CRCS Pamphlet, An Important Message To Our Blood Donors*); and

Ex. 637, CRC Vol. 34, Tab 20 (CRCS Pamphlet, An Important Message To Our Blood Donors, dated August 1985).

⁹³² *Evidence of Professor Tom Alloway, member of AIDS Panel, pp. 23751-23752, 23764-23765.*

at large were such that no public information leaflet about AIDS could even use the word "condom" for fear of causing offence.⁹³³ The language in such pamphlets could not be sexually explicit, particularly where it dealt with gay sexual activity.⁹³⁴ The issues of donor screening, direct questioning and content of pamphlets cannot be appreciated and analyzed without considering the social climate of the day.

541. The CRCS and other blood banks walked a fine line between politics and science. The message had to be delicate enough to appease a sensitive public at large. Discrimination against members of high-risk groups could only be justified by scientific data. The outcry after the March 1983 CDC publication in the United States and the CRCS press release in Canada is an example of the difficulties faced by the CRCS and other blood bankers.

⁹³³ Evidence of William Mindell, CHS Member (Ontario Chapter) pp. 32359-32361;

Evidence of Dr. Clayton, former member of NAC AIDS, pp. 41794-41798;

Evidence of Dale McCarthy, AIDS Panel, pp. 9697-9700;

Evidence of Mr. Landry, NB CHS Panel, pp. 11470-11471;

Evidence of Dr. Johnstone, former Director of Division of Epidemiology, Ministry of Health, B.C., pp. 4298-4306, 4415;

Evidence of David Kirkwood (Health & Welfare Canada Panel), pp. 43926-43928; and

Evidence of Colin Soskolne, NAC AIDS Panel, pp. 24916-24919.

⁹³⁴ Ex. 618, CRC Vol. 15, Tab 25 (Memo from Dr. Derrick to All Centre Medical Directors and Members of the CRC BTS Ad Hoc Working Group on AIDS, dated April 28, 1983);

Evidence of Kirkwood, (Health & Welfare Canada Panel) pp. 43926-43928;

Evidence of Dr. Gilmore, former NAC AIDS member, pp. 24916-24919; and

Ex. 586, Vol. 139, Part II, p. 16 (ACT pamphlet, dated 1983).

10) The Pressure of Corporate Challenges

542. The CRCS has always relied upon donors to act with honesty and personal responsibility to ensure that the Canadian blood supply is as safe as possible.

543. Corporate challenges to donate blood motivate well-intentioned donors to attend blood donor clinics. They are essential in ensuring that there is an adequate supply of safe blood. The danger is that members of high-risk groups may fail to self-defer because of fear of exposure before their colleagues. Inherent in the Donor Questionnaire are many ways that a donor can self-defer without embarrassment. A cold or the recent ingestion of aspirin can preclude donation. Therefore, donors need not feel pressure to donate if there is a risk to either themselves or the recipient.⁹³⁵ Moreover, the statistics show that many donors do not feel compelled to donate notwithstanding the "challenge". For example, in typical clinics held in high schools, only 50% of high school students attend the clinics. Many of those who do not attend cite fear of donation as the reason. Such persons are always encouraged to defer because those who are nervous about donating have a greater chance of adverse reactions or fainting.⁹³⁶ Turn-out at corporate challenges is often less than 40%, demonstrating that many donors feel free to choose not to donate.⁹³⁷

544. In the 1980's, the altruistic nature of a donation was believed sufficient to defer anyone in a high-risk group. It was only after the advent of HIV antibody testing that it was discovered that many people in high-risk groups donated notwithstanding their knowledge⁹³⁸.

⁹³⁵ Evidence of Ray Bradbury, Newfoundland BDR, pp. 14728-14729.

⁹³⁶ Evidence of Helen Dunne, Newfoundland BDR, pp. 14726-14727.

⁹³⁷ Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40834-40835; and

Ex. 334, Vol. 99, p. 200 (Memo from Andrew Fleming and George Weber to Blood Donor Recruitment Volunteers and Staff, CRCS), dated August 22, 1986.

⁹³⁸ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22544-22546.

545. Donor screening pamphlets contained a further protection: they contained a space for the CRCS centre to place a stamp with its telephone number on it, to allow donors to call the clinic after making a donation if they believed it ought not to be used for transfusion. This has always been the practice.⁹³⁹ This "call-back" procedure was formalized in the November 1986 CRCS donor screening pamphlet which specifically advised donors that they could call the centre if they decided at any time during or after the donation that their blood should not be used for transfusion, and provided a telephone number.⁹⁴⁰ Since the implementation of Confidential Unit Exclusion (hereinafter referred to as CUE), it has been easier for donors to ensure that their donations are not used if they think that their donations may not be safe for the recipient for any reason.⁹⁴¹

11) The Risk to Hemophiliacs and Their Sexual Partners

546. Since the CRCS had no contact with patients, it relied upon hemophilia treaters during the course of monitoring their patients to warn hemophiliacs and their sexual partners of the dangers of sexual transmission of the agent causing AIDS, as this knowledge developed.⁹⁴²

547. Sexual partners of hemophiliacs were not specifically excluded from donation until they were listed in the January 1986 CRCS pamphlet.⁹⁴³ The risk of AIDS to sexual partners of hemophiliacs was not obvious even in early 1985. There was uncertainty as to whether or

⁹³⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28235, 28293.

⁹⁴⁰ Ex. 647, CRC Vol. 44, Tab 14 ("AIDS New Information for All Blood Donors").

⁹⁴¹ A full discussion of CUE is contained later in this section.

⁹⁴² Ex. 761, Vol. 167, Tab 21 (Minutes of CHS MSAC Meeting, dated March 23, 1985); and

Ex. 765, Vol. 171, Tab 59 (Report from Dr. Card to Provincial Advisory Committee on AIDS, dated March 14, 1986).

See also the discussion under Hemophiliacs and Hemophilia Treaters contained in these submissions.

⁹⁴³ Ex. 642, Vol. 39, Tab 3 (CRCS pamphlet, AIDS New Information for all Blood Donors, dated January 1986).

not the disease could be efficiently transmitted through vaginal intercourse.⁹⁴⁴ Sexual partners of hemophiliacs were not deferred from donating until it became apparent in late 1985 through anti-HIV testing that many partners of hemophiliacs had been "exposed" to the virus. Even then, treaters of hemophiliacs and their sexual partners were more concerned about their immune status than their seropositivity.⁹⁴⁵ Many treaters at that time still believed that the presence of the antibody could be protective.⁹⁴⁶ Even in 1986, the risk was considered to be low for the AIDS virus because the state of knowledge was still such that it was believed that only a few of those exposed to the virus would go on to develop full-blown AIDS.⁹⁴⁷

⁹⁴⁴ Ex. 551, Vol. 125, Part II, Tab 7 (*de Shazo et al., "An Immunologic Evaluation of Hemophiliac Patients and Their Wives", in Annals of Internal Medicine 1983, pp: 159-164 at 163*);

Ex. 556, Vol. 129, Tab 13 (*Hemophilia Information Exchange, AIDS Update, January 1984*);

Ex. 550, Vol. 125, Part I, Tab 43 (*ECHO, Vol. 4, No. 1, May 1983, at p. 9*);

Ex. 550, Vol. 125, Part I, Tab 49 (*Harris et al, "Immunodeficiency in Female Sexual Partners of Men with The AIDS", in NEJM, May 19, 1983*);

Ex. 764, Vol. 170, Tab 2 (*Hemophilia Information Exchange, AIDS Update, September 1985*);

Ex. 756, Vol. 162, Tab 26 (*Hemophilia Ontario, March 1984*); and

Ex. 756, Vol. 162, Tab 19 (*Hemophilia Information Exchange, AIDS Update, February 3, 1984*).

⁹⁴⁵ Evidence of Dr. Tsoukas, *Montreal General Hospital*, pp. 39591, 39599-39601, 39605-39607, 39610-39612;

Ex. 552, Vol. 126, Tab 7 (Article, *Annals of Internal Medicine* entitled "AIDS in the Wife of a Hemophiliac", dated January 1984);

Ex. 756, Vol. 162, Tab 26 (*Hemophilia Today, "Special Issue on AIDS", dated March 1984*);

Ex. 761, Vol. 167, Tab 15 (Letter from Dr. Naylor to Mr. Gurney re: *Draft of the CHS Blood Products Policy*, dated March 15, 1985);

Ex. 761, Vol. 167, Tab 19 (Information Statement, "AIDS in Hemophiliacs", by Dr. Irwin Walker, dated March 22, 1985); and

Ex. 761, Vol. 167, Tab 21 (Minutes of *CHS Ontario Chapter MSAC Meeting*, dated March 23, 1985).

⁹⁴⁶ Ex. 764, Vol. 170, Tab 1 (News from *Hemophiliac Clinic, 1. Update on AIDS and 2. Blood Product Testing*, dated September, 1985).

⁹⁴⁷ Evidence of Dr. Tsoukas, *Montreal General Hospital*, pp. 39675-39678;

Ex. 947, Vol. 273, Tab 8 (Study by Dr. Tsoukas in 1986 published in *Annals of Internal Medicine*); and

548. In the spring of 1985, Dr. Card, as Chair of the National CHS Medical and Scientific Advisory Committee (MSAC), proposed that sexual partners of hemophiliacs be added to the list of high-risk groups on the CRCS donor screening pamphlet. This issue was discussed by the CRCS at the Donor Selection Criteria Working Group meeting of June 10, 1985, where it was agreed that because hemophiliacs were small in number, they be advised of the risk through Dr. Card and the CHS.⁹⁴⁸ The CRCS was sensitive to the wishes of hemophiliacs and their sexual partners to avoid further stigmatization of a community which had already been stigmatized, first by hemophilia and later by its association with AIDS.⁹⁴⁹ Even Bill Mindell, of the Toronto Board of Public Health, testified that public health officials did not counsel hemophiliacs to wear condoms during sexual intercourse, as they did with gay men, because they were not sure of the level of transmissibility and stated that these matters were up to the patient and his treating physician.⁹⁵⁰

549. At the April 19, 1985 CHS MSAC meeting, it was determined that sexual partners of hemophiliacs should not donate blood and that this information was to be widely disseminated

Ex. 812, Vol. 182, Part II, Tab 24 (*Medical Corner*, Fall of 1986, Articles entitled "HTLV-III (HIV) Antibody Testing and You" by J. Crump, RN, and Dr. Inwood, and "New Name for HTLV-III Virus" by Dr. Martin Inwood).

⁹⁴⁸ Ex. 636, CRC Vol. 33, Tab 4 (Minutes of Donor Selection Criteria Working Group Meeting, dated June 10, 1985).

⁹⁴⁹ Evidence of Dr. Strawczynski, former MSAC Chairman and Hemophilia Treater, p. 31107; and

Evidence of Dr. Perrault, former National Director BTS, pp. 29792-29793.

⁹⁵⁰ Evidence of Bill Mindell, CHS Member (Ontario Chapter), pp. 32377-32378.

throughout the CHS,⁹⁵¹ notwithstanding that the risk to sexual partners was not fully appreciated.⁹⁵²

550. In retrospect, given what is now known about the actual risk at the time, it would have been prudent to specifically exclude sexual partners of hemophiliacs from donating blood earlier. However, the perceived risk at the time was minimal, and the CRCS believed that the CHS and hemophilia treaters were already advising the small subset of donors who were sexual partners of hemophiliacs to self-exclude.⁹⁵³

12) Confidential Unit Exclusion

551. The Greater New York Blood Program (hereinafter referred to as "GNYBP") was the only blood centre in the world to implement CUE in 1983.⁹⁵⁴ In fact, it pioneered the procedure. The GNYBP did not have a typical donor base, even for the United States. In 1983, the New York region had 40% of the AIDS cases in the world. Consequently, more drastic steps were required in that area. Moreover, because of the significant gay population in the region, the GNYBP had already established a relationship with the community and implemented CUE after consultation with and consent from the gay community.⁹⁵⁵

⁹⁵¹ Ex. 763, Vol. 169, Tab 21 ("Hemophilia Ontario", July - September 1985);

Ex. 763, Vol. 169, Tab 43 ("Hemophilia Today", August 1985);

Ex. 765, Vol. 171, Tab 38 (CHS Newsletter, "AIDS and Hemophilia", dated February 1986); and

Ex. 765, Vol. 171, Tab 52 ("Hemophilia Today", March 1986).

⁹⁵² Ex. 761, Vol. 167, Tab 53 (Minutes of CHS MSAC Meeting, dated April 19, 1985); and

Ex. 761, Vol. 167, Tab 55 (CHS MSAC Statement, dated April 19, 1985, "Status of AIDS and Hemophilia").

⁹⁵³ Evidence of Dr. Perrault, former National Director BTS, p. 29794.

⁹⁵⁴ Ex. 620, CRC Vol. 17, Tab 26 (Letter from Dr. Pindyck (GNYBP) to Dr. Derrick, dated August 5, 1983).

⁹⁵⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30921-30924.

552. The results of the GNYBP (Pindyck) CUE study suggested that this procedure may be targeting members of high-risk groups. Approximately 3% of all units collected by the GNYBP during the three-month CUE project from March to May 1983 were designated "not for transfusion". 70% of these units were donated by males. Young men, in particular, excluded their donations from transfusion at a significantly higher rate.⁹⁵⁶ Nonetheless, these results did not prompt blood banks across the United States or the CRCS, to implement CUE. There was no way to quantify the effectiveness of CUE until the implementation of anti-HIV testing as its sensitivity and specificity were unknown until then.⁹⁵⁷

553. The seminal study which prompted the FDA to recommend CUE in 1986, was conducted by the CRCS. With anti-HIV testing, the efficacy of CUE could be determined.⁹⁵⁸ The Toronto Centre self-designation (hereinafter referred to as the "Nusbacher") study was conducted from September 1985 to March 1986.⁹⁵⁹ The Nusbacher study results indicated that CUE was an effective means of eliminating high-risk donors from the blood supply. After the results of the study were published, the FDA issued a recommendation in support of CUE in October 1986.⁹⁶⁰ Prior to the FDA recommendation, CUE was used only sporadically by a few blood banks. After the FDA recommendation, there was only one blood bank in the United States which did not use CUE.⁹⁶¹

⁹⁵⁶ Ex. 746, Tab 2 (*CCBC Newsletter*, dated September 9, 1983) re: GNYBP CUE Study; and

Ibid, Tab 3 (*Article in Transfusion*, 1983 entitled, "Measures to Decrease the Risk of Acquired Immune Deficiency Syndrome Transmission by Blood Transfusion", by Pindyck et al).

⁹⁵⁷ Evidence of Dr. Davey, former Assistant National Director BTS, p. 28724.

⁹⁵⁸ Evidence of Dr. Davey, former Assistant National Director BTS, p. 28724, 30924-30927.

⁹⁵⁹ Ex. 746, Tab 22 (*Article in Transfusion*, 1986, "Evaluation of a Confidential Method of Excluding Blood Donors Exposed to Human Immunodeficiency Virus", by Nusbacher et al).

⁹⁶⁰ Ex. 746, Tab 24 (FDA Recommendations dated October 30, 1986 re: Additional Recommendations for Reducing Further the Number of Units of Blood and Plasma Donated for Transfusion or for Further Manufacture by Persons at Increased risk of HTLV-III/LAV Infection).

⁹⁶¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22412-22415.

554. The CRCS sought approval in 1987 from the CBC for funding for "enhanced donor screening measures" for the 1988-1989 budget year. "Enhanced donor screening" included hiring more nurses to conduct donor screening and receiving greater resources to implement CUE, including privacy stations. The CRCS had experienced difficulty ensuring adequate privacy at mobile clinics, which were makeshift arrangements run out of church basements, etc. Permanent clinics, long overdue for money for renovations, were not much better.⁹⁶² In requests for funding, the CRCS ran into an obstacle: the CBC, which initially rejected the requests.⁹⁶³ The CBC believed that the number of nurses at each clinic was already sufficient and there was no justification for expending additional funds for CUE. It was not until the May 16, 1989 CBC meeting that enhanced donor screening, with sufficient resources to implement CUE, was endorsed by the CBC for the 1989-1990 year.⁹⁶⁴

555. CUE was controversial both in the United States and Canada before it was implemented. Some blood bankers were concerned that its use would encourage high-risk donors to attend at blood donor clinics to make a public gesture without risk to the blood supply. Others worried about exposure of laboratory workers to more risky blood from donors who decided to make a donation but signified that the blood was "not for transfusion". Still others questioned its effectiveness.⁹⁶⁵ Subsequent data has shown that while CUE did have a short

⁹⁶² Evidence of Dr. Perrault, former National Director BTS, and evidence of Dr. Davey, former Assistant National Director BTS, pp. 27361-27362, 28027-28032, 28167-28168, 28479-28480, 28512-28514; and Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 410-412.

⁹⁶³ Ex. 866, Vol. 198, Tab 6, p. 3 (Minutes of CRCS Senior Management and CBC Secretary Meeting, dated September 22, 1988); and

Ibid., Vol. 198, Tab 7, p. 3 (Minutes of CBC Meeting, dated September 28, 1988).

⁹⁶⁴ Ex. 867, Vol. 199, Tab 5, p. 2 (Minutes of CBC Budget Sub-committee meeting of May 4, 1989); and
Ibid., Vol. 199, Tab 6, p. 7 (Minutes of CBC Meeting of May 16-18, 1989).

⁹⁶⁵ Ex. 746, Tab 20 (Letter from Gail Rock to Dr. Perrault dated July 28, 1986);
Ex. 746, Tab 21, p. 2 (CCBC Newsletter, dated August 1, 1986);
Ex. 746, Tab 23 (Memo from Dr. Schroeder to Dr. Perrault dated October 15, 1986); and

term effect it no longer is effective.⁹⁶⁶ The FDA has since withdrawn its support for CUE.⁹⁶⁷ Nonetheless, once a donor screening measure is implemented political considerations make it difficult, even impossible, to discontinue it.

13) Donor Screening Comparisons and Evaluating CRCS Measures

556. While in 1983 and 1984, CRCS donor screening measures differed from some of those in other countries, in particular the United States, the data demonstrates that the CRCS did as well, or even better, than most other countries, as measured by incidence of TAA and AIDS associated with component therapy.⁹⁶⁸

Ex. 746, Tab 28 (Memo from Dr. Culver-James to Dr. Perrault, dated September 20, 1988).

⁹⁶⁶ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22546-22547; and

Evidence of Dr. Perrault, former National Director BTS, and Dr. Davey, former Assistant National Director BTS, pp. 28523, 30927-30932.

⁹⁶⁷ Ex. 746, Tab 36 (FDA Recommendations, dated April, 1992 re: Recommendations for the Prevention of HIV Transmission by Blood and Blood Products).

⁹⁶⁸ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27074-27075, 29540, 31014-31019;

Evidence of Dr. Perrault, former National Director BTS, pp. 29540-29542; and

Ex. 715, Vol. 155 (*International Overview of Donor Screening Measures Introduced in 1983*).

Ex. 748 (*National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey*);

Ex. 1028, Vol. 286, Tab 7 (*Comparative Analysis of AIDS Incidence, Total and Associated with Clotting Factors and Transfusion, cumulative to March 1995 for selected countries in North America, Europe and Oceania, dated August 11, 1995, by Dr. Remis*);

Ex. 1039 (Remis data, dated October 12, 1995, titled "Comparative Analysis of rates of AIDS including AIDS associated with transfusion and clotting factors among 20 countries of Western Europe (including all countries with populations greater than million), North America and Australia, December 1994-April 1995");

Ex. 1278, ("An International Comparison of the Incidence of AIDS Associated with Blood and Blood Products", Abstract of Poster Presentation by Martin Davey from the annual meeting of the Canadian Society for Transfusion Medicine, 24-26 May 1996);

Ex. 1279, ("An International comparison of transfusion-associated HIV infection: How well did Canada Do?", by Robert Remis and Alain Vandal)

557. Dr. Davey evaluated and prepared the rates of AIDS in 21 developed countries, including Canada, in which such data was accurate and comparable. The data shows that the United States has by far the greatest rate of AIDS per million population. Canada has a rate of less than one-quarter the U.S. rate, taking into account the population differences.⁹⁶⁹

558. The data also presents a comparison of the rates of TAA and AIDS due to component therapy in various countries. The Australian rate of TAA is not significantly different than the Canadian rate, despite the fact that the Australian rate for AIDS overall is about 15% lower than the Canadian rate. Similarly, comparable rates of TAA are found in Belgium, Portugal and Denmark, despite those countries having a lower rate of AIDS in general. The American rate of AIDS due to transfusion is over three times the Canadian rate.⁹⁷⁰

559. The conclusion to be drawn is that Canadian donor screening measures were at least as effective as those in the U.S. and Australia, Belgium, Portugal and Denmark.⁹⁷¹

Ex. 1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4.

⁹⁶⁹ *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 3101-31011; and*

Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey).

Ex. X1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4.

⁹⁷⁰ *Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey); and*

Evidence of Dr. Davey, former Assistant National Director BTS, p. 31016.

Ex. X1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4.

⁹⁷¹ *Ex. 715, Vol. 155 (International Overview of Donor Screening Measures introduced in 1983);*

Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey);

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 31017-31018;

Ex. X1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4; and

Ex. X1279, An International comparison of transfusion-associated HIV infection: How well did Canada Do? by Robert Remis and Alain Vandal.

560. The data with respect to the rate of AIDS due to the use of clotting factors is significantly different. The Canadian rate is just over half the U.S. rate, while the Australian rate is much lower. These rates can be explained by the fact that Australian hemophiliacs used no U.S. origin clotting factors, whereas Canadian hemophiliacs used approximately 50% of product originating from the U.S.⁹⁷² All countries which used Factor VIII concentrates derived from U.S. plasma have higher incidence of AIDS in hemophiliacs than countries which used only clotting factors made from local plasma.⁹⁷³

561. The data by both Dr. Remis and Dr. Davey supports Dr. Davey's testimony that the Canadian incidence of TAA has been less than many, and comparable to, most of the 21 other developed countries surveyed.⁹⁷⁴ These data and conclusions accord with those in Dr. Remis' study of the same countries, which was also presented at the Inquiry and which has since been expanded upon and updated.⁹⁷⁵

562. Statistics on the Canadian HIV detection rate for 1991 to 1993 support the view that CRCS donor screening measures weeds out high-risk donors in Canada. Despite general community epidemiological statistics that show an increasing incidence of HIV in the overall

⁹⁷² Evidence of Dr. Davey, former Assistant National Director BTS, pp. 31019-31020; and

Ex. 748 (National Rates of AIDS: Reported cases to 1994, developed countries, by Dr. Davey).

Ex. X1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4.

⁹⁷³ Ex. X1301, Expert Report of Dr. Davey, dated August 2, 1996 in CRCS at Osborne/Walker, pp. 3-4.

⁹⁷⁴ Ex. X1279, An International comparison of transfusion-associated HIV infection: How well did Canada Do? by Robert Remis and Alain Vandal.

⁹⁷⁵ Ex. 1028, Tab 7 (Comparative Analysis of AIDS Incidence, Total and Associated with Clotting Factors and Transfusion, cumulative to March 1995 for selected countries in North America, Europe and Oceania, dated August 11, 1995, by Dr. Remis);

Ex. 1039 (Remis data, dated October 12, 1995, titled "Comparative Analysis of rates of AIDS including AIDS associated with transfusion and clotting factors among 20 countries of Western Europe (including all countries with populations greater than million), North America and Australia, December 1994-April 1995); and

Ex. X1279, An International comparison of transfusion-associated HIV infection: How well did Canada Do? by Robert Remis and Alain Vandal.

population, the incidence of HIV has plateaued in the donor population. This suggests that the donor screening procedures in place are successful in limiting donations from those at high risk for AIDS.⁹⁷⁶

563. This data demonstrates that CRCS did as well or better than other countries which instituted donor screening measures such as symptom-specific questions, as measured by incidence of TAA and AIDS in hemophiliacs. Therefore, criticism of the "good health approach" of the CRCS is ill-founded. In every country studied, regardless of the donor screening measures instituted, the single most effective measure for reducing the incidence of TAA or AIDS due to clotting factors, was the introduction of anti-HIV testing.⁹⁷⁷

⁹⁷⁶ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 858-860; and

Ex. 14 (*Transmissible Disease Relative Rates for 1991-1993*).

⁹⁷⁷ Evidence of Dr. Davey, former Assistant National Director BTS, p. 31015;

Ex. 1301, *Expert Report of Dr. Davey*, dated August 2, 1996 in CRCS ats Osborne/Walker, pp. 3-4;

Ex. 1278, "An International Comparison of the Incidence of AIDS Associated with Blood and Blood Products," Abstract Poster Presentation by Martin Davey from the annual meeting of the Canadian Society for Transfusion Medicine, 24-26 May 1996; and

Ex. 1279 "An International comparison of transfusion-associated HIV infection: How well did Canada Do?" By Robert Remis and Alain Vandal.

C.

SURROGATE TESTING FOR AIDS

564. Surrogate tests for AIDS proposed in 1983 were of two varieties: (1) those that detected the potential pre-clinical stages or abnormalities associated with the disease; and (2) those that detected evidence of past infections with diseases that had a high incidence in the same groups that were at increased risk for AIDS. Surrogate tests are, in essence, indirect tests.

565. Before the virus causing AIDS was isolated and anti-HIV testing developed, knowledge as to the degree of risk of AIDS from blood was very limited, but was believed to be remote.⁹⁷⁸ This belief was supported by the absence of a single case of TAA in Canada and only two cases of AIDS in hemophiliacs.⁹⁷⁹ Utilizing surrogate tests for AIDS was generally not supported by blood bankers since there was little evidence that surrogate tests for AIDS would be effective or that the associated expense was justified. The significant loss to the donor pool was considered to be unacceptable given the lack of proven efficacy of tests, the belief that the risk of AIDS was low, and that self-deferral was an effective strategy.

1) The Case In Favour of Surrogate Testing for AIDS

566. Those who advocated the implementation of surrogate testing relied on the data generated by Dr. Thomas Spira of the CDC to support the view that some surrogate tests, in particular the hepatitis B anti-core test (anti-HBc), were sensitive and specific enough to be useful surrogate tests for AIDS. Dr. Spira presented his data on a variety of potential surrogate tests, including anti-HBc, at the January 4, 1983 Working Group to Identify Opportunities for Prevention of AIDS, hosted by the HHS (CDC). This data showed that 88.2% of the

⁹⁷⁸ See Section on Developing Knowledge of Science and Risks in this paper.

⁹⁷⁹ Ex. 552, Vol. 126, Tab 33, p. 126 (LCDC AIDS Update, dated April 19, 1984).

gay/bisexual sample population used for his study were positive for anti-HBc, as opposed to only about 5% of the normal control group.⁹⁸⁰

567. Proponents of surrogate testing argued that, while the concrete data as to its efficacy had not yet been established, surrogate testing would provide the following valuable benefits:

- surrogate testing would probably result in the prevention of some cases of transfusion-associated AIDS, although how many was uncertain⁹⁸¹;
- surrogate testing would increase public confidence⁹⁸² because blood banks would at least be making some attempt to use an objective test to separate high-risk donors from those who were not high risk for AIDS⁹⁸³;
- surrogate testing might increase, marginally, the number of donors who were excluded for hepatitis B and were not detected by the hepatitis B surface antigen test⁹⁸⁴;
- surrogate testing did not require intrusive questioning of donors and therefore respected their privacy⁹⁸⁵; and
- surrogate testing was convenient because tests could be done on specimens already drawn for hepatitis B surface antigen testing⁹⁸⁶.

⁹⁸⁰ Ex. 554, Vol. 128, Part I, Tab 2 (*Documents from Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 48*).

⁹⁸¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22452.

⁹⁸² Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22452.

⁹⁸³ Ex. 554, Vol. 128, Part I, Tab 2 (*Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p.19*).

⁹⁸⁴ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22452.

⁹⁸⁵ Ex. 554, Vol. 128, Part I, Tab 2 (*Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 19*).

⁹⁸⁶ Ex. 554, Vol. 128, Part I, Tab 2 (*Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 19*).

2) The Case Against Surrogate Testing for AIDS

568. Despite the above points, the overwhelming view shared by blood bankers, transfusion experts, and regulators worldwide, both then and now, was that there was insufficient evidence to justify implementation of any of the surrogate tests for AIDS. Surrogate tests were too non-specific; the studies were not sufficiently supportive of the conclusion that surrogate tests ought to be introduced.

569. Surrogate tests did not target donors with AIDS. Rather they attempted to remove those who were in the same high-risk groups. Therefore, they were highly non-specific. Many surrogate tests other than anti-HBc were proposed and studied by Dr. Spira, such as absolute lymphocyte count, T-helper/T-suppressor ratio, and immune complex assays. Stanford University began using the T4/T8 ratio to screen blood donations sometime in 1983, but it was the only blood bank to do so. Even there, not every recipient of blood at Stanford University Hospital received screened blood. Because it collected only half of the blood used by the hospital, the remainder was collected elsewhere; accordingly, only half of the blood infused into patients was tested for T4/T8 ratio. The equipment used to screen blood donations in this manner was very expensive and required someone with a PhD to operate it. Consequently, this measure was out of the financial reach of most blood banks.⁹⁸⁷ Moreover, it was not considered to be as sensitive or specific as the hepatitis B anti-core test. Although the anti-HBc was considered to be the better test according to Dr. Spira's data, it had the downside of deferring approximately 5% of healthy donors.⁹⁸⁸

⁹⁸⁷ Evidence of Dr. Francis, former Director of Division of Blood and Blood Products, FDA, pp. 21804-21805; and

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22719.

⁹⁸⁸ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22437-22438; and

Ex. 554, Vol. 128, Part I, Tab 2 (Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 48).

570. Dr. Spira's study was heavily criticized. The study population was a group of gay and bisexual men who attended a sexually transmissible disease clinic. Consequently, there was a bias inherent in his data, which made the test appear to be more specific than it really was.⁹⁸⁹ In a normal donor population in which the rate of hepatitis B would be expected to be substantially lower than in a gay or bisexual population, the test would be less specific and most of the positive test results would be 'false positives'. This would result in a significant number of healthy donors being deferred unnecessarily. Dr. Zuck described it this way:

...in the case of throwing out blood that is perfectly good, specificity is the relevant determinant...

And I think I testified that I am not sure how Spira defined sensitivity and specificity...

Because those are population driven. You have to know the prevalence of a disease before you can calculate sensitivity and specificity...

So, it is going to be very, very different for sexually active homosexual men with multiple sex partners, as in an STD clinic, than the normal blood donors that walk through the door. It was the context I was making in the statement...

Let's try and go backwards. This chart was made up in response -- or reflecting data in his sexually transmitted disease clinic. It is a clinic when virtually everybody that has a positive test for anti-core, will in fact have been infected with hepatitis; okay?...

That is the specificity issue. Virtually everybody, because sensitivity and specificity are defined by the prevalence of the disease in the population for every test but HIV antibody...

In terms of sensitivity, it is also highly sensitive because of the fact that the antibody has a high prevalence. And the miss rate for that test is relatively low. The percentage in a normal blood donor's is very, very different. So, when you say -- when he says -- Tom Spira says it is got a high sensitivity, and high specificity it is in a population with a very high prevalence for the disease, okay?

...Now, let's translate that over to a normal blood donor, or take a cohort of normal blood donor -- or many -- let's take the same number of normal blood donors who walk down the pike, as he had in his STD clinic, okay? Virtually none of the people that have reactivity the anti-core will in fact have been infected with hepatitis B virus. Because, in a normal -- it is the prevalence of hepatitis B infection in the normal blood population is extraordinarily small. And the smaller the prevalence becomes the less specific comes the test.

⁹⁸⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 29305-29306.

So, virtually all the tests that the anti-core would have screened out in a blood banking setting, with normal donors, would have been false positive. Now, the argument against that is that if there is a high population of gay men, who shouldn't be in your blood centre but still are, then that would increase the specificity of the test.⁹⁰

571. Even Dr. Spira's conclusion in the paper he submitted for publication to the *New England Journal of Medicine*, but which was rejected, does not whole-heartedly endorse surrogate testing for all blood banks. Rather, he speaks of the necessity of weighing the costs against the benefits of such tests:

The cost vs. benefits for screening tests may vary greatly depending upon the geographic location and the nature of the population served. The distribution of potential AIDS transmitters in donor populations in certain areas may be higher than others, making screening more valuable in the former than the latter. Even within high risk areas, screening frequent or plasmapheresis donors is likely to be more cost effective than screening donors of single units. In addition, some screening tests may have other benefits as well - e.g. anti-HBc testing may have a non-specific role in the reduction of non-A, non-B hepatitis, as well as hepatitis B transmitted by blood donors.

The risk of transmitting disease via a unit of blood from a known AIDS patient is unknown, but it is thought to be low. Prospective studies of screening for individuals with potential for transmitting AIDS should take these issues into consideration.⁹¹

572. Other data available at about the same time was less favourable than Dr. Spira's. A study conducted by Dr. James Pert was reported to Dr. Curran of the CDC in January of 1983. Dr. Pert examined 53 gay males in an STD clinic in upper New York State, of whom only 20.8% were positive for anti-HBc. He concluded that it was unlikely that anti-HBc screening for gay men would be effective in screening for AIDS in the future.⁹² The same criticisms may be made of Dr. Pert's data as Dr. Spira's data. His study group was also gay males who presented themselves at an STD clinic. Nonetheless, it is significant that the

⁹⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22830-22833.

⁹¹ Ex. 562, Tab 31 ("Evaluation of Potential Screening Tests: Reducing the Risk of Transmission of AIDS through Blood or Blood Products", by Dr. Spira et al, undated, at pp. 9-10).

⁹² Ex. 554, Vol. 128, Part I, Tab 7 (Letter from Dr. James Pert to Dr. James Curran, dated January 6, 1983, at p. 67).

prevalence of anti-HBc in Dr. Pert's study population was substantially lower than that found in Dr. Spira's study population. This study certainly put into question Dr. Spira's results and increased the uncertainty many felt about the efficacy of surrogate testing.⁹³

573. Around the same time, a Dr. Perkins from San Francisco conducted what has become known as the "Zip Code Study". Dr. Perkins' data showed that the difference in anti-HBc prevalence in predominantly heterosexual versus gay neighbourhoods, as designated by zip code, was not significant.⁹⁴

574. The difficulty with such studies was that they left the scientific evidence in a state of uncertainty. The costs as measured in dollars and donor deferral rates were known. The efficacy of the tests in weeding out donors at risk for AIDS, as opposed to individuals in the same high-risk groups, was not known. There was a real fear that the implementation of a surrogate test would serve to invite high-risk donors to a blood clinic to be tested. Given all these factors, which had to be considered before a new test was implemented to screen blood, surrogate testing did not receive widespread support:

Let's take the most obvious down side first. The most obvious down side is that if the ZIP code data of San Francisco is correct, the efficacy is very low. If the data from CDC, Tom Spira's data is correct, the efficacy might be very high. The difficulty is we are not sure which one is the right answer, and we are not sure why the variance.

So first of all, I think people were concerned that the efficacy might not even be 20 per cent, it might be much lower.

The second difficulty is, if we had been, and we believed we were at the time, if we had been successful in asking men at risk not to donate blood, and we now offer this test as a surrogate test for AIDS, understanding there is no real test for AIDS, the question we asked ourselves: would we in fact, invite people to donate blood to get an anti-core test to find out whether they might be infected. These people might come in to get tested, and they wouldn't have come otherwise. And if they are in some sort of window period, this period where they don't have anything we can detect, then we might make the blood supply less safe.

⁹³ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22446-22447.

⁹⁴ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22448.

This is a serious concern because we know there is test seeking, then studies that had been done in several different settings -- I can quote them for you -- the Susan Lightman study, Dr. Doll's studies, and now in the REDS data base, we know there is test seeking, people coming to blood centres to get tested. So that we know it is a real phenomenon, we just, in this case, weren't sure whether we would make the blood supply less safe or more safe if we weren't sure of the efficacy.⁹⁵

575. A study published in May 1984 *Transfusion* concluded that, "Surrogate tests for AIDS are nonspecific and unlikely to be helpful in screening blood donor units". Moreover, it would result in the exclusion of 15 to 20% of plasma donors and 3% of volunteer whole blood donors.⁹⁶

576. Only a handful of blood banks, primarily in the San Francisco Bay area, instituted hepatitis B anti-core testing as a surrogate test for AIDS. The Peninsula Bay Memorial Blood Bank also began anti-core testing on April 2, 1984. Irwin Memorial Blood Bank began on May 1, 1984.⁹⁷ This was followed by the only American Red Cross Centre to implement surrogate testing, the San Jose Centre. This Centre was reportedly compelled to begin anti-core testing because the other clinics in that area had done so. This decision was based on the political environment, not on science.⁹⁸ It is significant that Cutter was the only fractionator to do so when it implemented anti-HBc testing on April 2, 1984.⁹⁹ Because of the competition among

⁹⁵ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22449-22451.

⁹⁶ Ex. 552, Vol. 126, Tab 34 (Simon and Bankhurst, "A Pilot Study of Surrogate Tests to Prevent Transmission of AIDS by Transfusion," in Transfusion, Vol. 24, No. 5, at p. 373).

⁹⁷ Ex. 556, Vol. 129, Tab 29 (CCBC Newsletter, dated April 6, 1984, at p. 111).

⁹⁸ Ex. 571, Vol. 132, Tab 28 (Memo from Barbara Buchner to Dr. Naylor, dated April 10, 1984 re: pre-test of Donor Blood for Anti-HBc); and

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22457-22458.

⁹⁹ Ex. 556, Vol. 129, Tab 29 (CCBC Newsletter, dated April 6, 1984).

Cutter later discontinued anti-HBc testing because it could not meet the requirements of a certain level of HBsAg antibody to counteract any virus in the immune globulin. Removing anti-core inevitably resulted in the removal of anti-surface, which made the immune globulin less safe - See Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22456-22457.

the various commercial fractionators. It is surprising that only one fractionator chose to implement anti-HBc testing. This supports the view that the evidence in favour of surrogate testing for AIDS was shaky.

577. In spite of the fact that a handful of blood banks instituted surrogate testing, none of the public health agencies in the United States (CDC, NIH, FDA or HHS) recommended surrogate testing for AIDS. In fact, the NIH operated an FDA-licensed hospital blood bank on its premises and did not institute surrogate tests for AIDS there.¹⁰⁰⁰

578. Assistant Secretary of Health (HHS), Edward Brandt wrote in June 1983:

There appears now to be no link between anti-core and AIDS other than that hepatitis and AIDS occur in groups which partially overlap. As a result, I believe there is now a general consensus by experts in this area that anti-core is unsatisfactory as a screening test for AIDS carriers.¹⁰⁰¹

Dr. Brandt also testified at the Hearings before a Subcommittee of the Committee on Operations on August 1 and 2, 1983 that no surrogate test was sensitive or specific enough to be useful.¹⁰⁰²

579. There was far from unanimous support for surrogate testing even within the CDC, despite the fact that Dr. Spira was employed by the CDC. The recommendations generated at

¹⁰⁰⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22371-22372, 22461;

Ex. 550, Vol. 125, Part I, Tab 27 (MMWR, dated March 4, 1983);

Evidence of Dr. Francis, former Epidemiologist, CDC, pp. 22168-22169; and

Ex. 562, Tab 27 (Evidence of Dr. Brandt, at Hearings Before a Subcommittee of the Committee on Government Operations, dated August 1 and 2, 1983, p. 484).

¹⁰⁰¹ Ex. 562, Tab 23 (Letter from Edwardh Brandt to Virginia Apuzzo, dated June 15, 1983, at p. 2).

¹⁰⁰² Ex. 562, Tab 27 (Federal Response to AIDS: Hearings before a Subcommittee of the Committee on Government Operations, dated August 1 and 2, 1983, at p. 484).

the January 4, 1983 Work Group to Identify Opportunities for the Prevention of AIDS indicate that participants had differing perceptions of, among other things, the best approach for establishing guidelines for blood donation, donor screening and testing. No recommendation was made at that meeting, or at any other time, by the CDC in favour of surrogate testing for AIDS.¹⁰⁰³ There was a split in opinion at the CDC. Those in favour of surrogate testing were Donald Francis, Bruce Evatt and Thomas Spira. However, their opinion never found favour with the majority of scientists at CDC.¹⁰⁰⁴ Even Bruce Evatt, when reporting on a meeting of the American Blood Commission Board of Directors on December 14, 1983, wrote that instituting surrogate tests for AIDS was controversial. There were a number of tests that could select out *those in high-risk groups* at the expense of an additional donor deferral rate of 5 to 7%.¹⁰⁰⁵

580. An FDA Blood Products Advisory Committee (BPAC) meeting on December 15 and 16, 1983 recommended that only the fractionation industry consider surrogate testing. It was not considered to be feasible for volunteer blood centres and was considered unwarranted, considering the data which showed that the risk of AIDS to transfusion recipients was very low compared to the risk to hemophiliacs. This committee concluded that, based on Dr. Spira's data, surrogate tests were insufficiently specific to be recommended.¹⁰⁰⁶

581. On March 6, 1984, an *ad hoc* committee of representatives from the volunteer blood banks, plasma fractionation industry and the U.S. federal government met to discuss the feasibility of surrogate tests. This committee meeting was sponsored by the FDA and the

¹⁰⁰³ Ex. 554, Vol. 128, Part I, Tab 2 (*Summary Report on Work Group to Identify Opportunities for Prevention of AIDS*, dated January 4, 1983, at pp. 17-20).

¹⁰⁰⁴ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22371-22372.

¹⁰⁰⁵ Ex. 556, Vol. 129, Tab 71 (*American Blood Commission, Status of AIDS and Transfusion*, by Bruce Evatt, dated December 14, 1983, at p. 296).

¹⁰⁰⁶ Ex. 555, Vol. 128, Part II, Tab 53 (*CCBC Newsletter*, dated December 16/23, 1983, at pp. 267-268).

National Heart, Lung, and Blood Institute (NHLBI). This committee did not recommend the implementation of surrogate tests for AIDS.¹⁰⁰⁷

582. One month later, at a meeting on April 12 and 13, 1984, as a follow-up to the December 1983 BPAC meeting, and in response to the announcement that some plasma and blood collections centres had begun voluntary anti-core testing, BPAC members participated in a conference call to discuss surrogate testing. The FDA was still not prepared to endorse the use of hepatitis B anti-core testing as a screen for AIDS in blood and plasma collection:

The recent decision by several blood and plasma organizations to use the anti-core test was a voluntary decision on their part with the recognition of the limitations of the test and the lack of data to support the premise that excluding anti-core positive individuals from donor pools will have any impact on the frequency with which donors are later found to have developed AIDS.

At this point, it would seem reasonable to continue voluntary and cooperative efforts aimed at assessing the potential usefulness of a variety of laboratory tests for their predictive value in identifying individuals who are in a pre-clinical stage of AIDS. On the basis of the information available to date, it is possible that screening tests other than anti-core may ultimately prove to be more predictive and generally useful in improving the safety of blood and blood products. It would therefore be unwise to adopt anti-core testing to the exclusion of other screening tests.¹⁰⁰⁸

583. The American Blood Resources Association (ABRA), the organization which represents the interests of the commercial fractionators, did not recommend the use of surrogate tests.¹⁰⁰⁹

584. Factors influencing the decision not to implement surrogate tests for AIDS included the following:

¹⁰⁰⁷ Ex. 556, Vol. 129, Tab 18 (*CCBC Newsletter*, dated February 10, 1984); and

Ex. 556, Vol. 129, Tab 29 (*CCBC Newsletter*, dated April 6, 1984, at p. 112).

¹⁰⁰⁸ Ex. 556, Vol. 129, Tab 39 (*Excerpt from AABB News Briefs*, dated May 3, 1984, at p. 185).

¹⁰⁰⁹ Ex. 554, Vol. 128, Part I, Tab 32 (*ABRA Newsletter*, dated January 28, 1983, at p. 198); and

Ex. 562, Tab 11 (*CCBC Newsletter*, dated February 4, 1983).

- the efficacy of surrogate tests had not been established;¹⁰¹⁰
- surrogate tests would result in substantial costs in loss of donors;¹⁰¹¹
- surrogate tests could add risk to the blood supply as a result of new more risky donors being recruited to replace regular donors who were deferred (which risk would be increased more if the deferred donor was a woman and the replaced donor was a man under the age of 35);¹⁰¹²
- such tests would add expense to the whole blood collection process;¹⁰¹³
- the non-specificity of surrogate tests would result in unnecessary deferrals so that most persons who tested positive would not truly have the antibody and this would cause unnecessary fear in and stigmatization of many donors;¹⁰¹⁴
- surrogate tests could produce a magnet effect whereby high-risk donors might come to the blood clinic to be tested;¹⁰¹⁵ and
- removing anti-core from immune globulin would decrease its safety since it would leave the hepatitis B antigen alone.¹⁰¹⁶

585. It was Dr. Derrick's responsibility to keep up-to-date on U.S. developments. He was in regular contact with staff at the CDC and attended many of the U.S. meetings where

¹⁰¹⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22453-22456.

¹⁰¹¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22453-22456.

¹⁰¹² Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22453-22456.

¹⁰¹³ Ex. 554, Vol. 128, Part I, Tab 2 (Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 19).

¹⁰¹⁴ Ex. 554, Vol. 128, Part I, Tab 2 (Summary Report on Work Group to Identify Opportunities for Prevention of AIDS, dated January 4, 1983, at p. 19).

¹⁰¹⁵ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22453-22456.

¹⁰¹⁶ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22453-22456; and

Ex. 563, Tab 1 (Letter from Dr. Petricciani to the Alpha Therapeutic Corporation, dated May 3, 1983).

these issues were discussed, after which he reported back to National office.¹⁰¹⁷ These issues were also widely reported in many of the journals, such as CCBC Newsletters and AmCross Blood Services letters, which the CRCS National office received regularly.¹⁰¹⁸ After an internal review of the evidence by CRCS National Office staff, the CRCS decided not to pursue the issue of surrogate testing for AIDS.¹⁰¹⁹ No American agency recommended that surrogate testing be done. Even in the United States, hepatitis B anti-core testing was limited to blood banks in a small, notably high-risk geographical area. Dr. Curran (CDC) said the following when he testified before the Sub-Committee on Health and Safety in 1990:

Anticipating that a good AIDS test would soon be available, the argument between March of 1983, and perhaps April of 1984, was whether a surrogate test should be used in blood banks.

My opinion is that, as a uniform national policy, it would have been unwise and unmanageable to attempt to utilize surrogate tests.¹⁰²⁰

586. Finally, in October 1996 Drs. Zuck and Eyster summarized the surrogate testing debate as follows:

The Report [IOM Crisis in Decisionmaking] implies that early-warning signals raised by the CDC were ignored and makes recommendations on the basis of

¹⁰¹⁷ Evidence of Dr. Perrault, former National Director BTS, and evidence of Dr. Davey, former Assistant National Director BTS, pp. 27286, 27320-27322, 27331-27332;

Ex. 616, CRC Vol. 13, Tab 12 (Trip Report by Dr. Derrick to NHF Industry Strategy Meeting on AIDS, dated January 14, 1983);

Ex. 618, CRC Vol. 15, Tab 7 (Trip Report by Dr. Derrick to NIH Interagency Technical Committee Working Group on Blood Resources and Blood Substitutes - 7th Meeting, dated April 6, 1983); and

Ex. 620, CRC Vol. 17, Tab 9 (Trip Report by Dr. Derrick to BPAC Meeting on the Safety and Purity of Plasma Derivatives, dated July 19, 1983).

¹⁰¹⁸ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27119-27120.

¹⁰¹⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27347-27350.

¹⁰²⁰ Ex. 562, Tab 43 (Hearings before the Subcommittee on Health and Safety of the Committee on Education and Labour, House of Representatives 101st, Congress, Second Session, January 24, 31 and May 24, 1990 at p. 113).

this implication. The Report also implies that blood collection agencies rejected suggestions made in 1983 by CDC scientists that direct questions about donors' sexual preferences be asked and that surrogate testing of donated blood with antibody to hepatitis B core antigen (anti-HBc) be implemented. However, neither CDC nor any other PHS agency made such recommendations. If the PHS, through CDC or FDA, had done so, the blood collection agencies almost certainly would have implemented the recommendations. It is true that at a meeting in January 1983, individual scientists associated with CDC (among them Thomas Spira, MD) did present data on surrogate tests for AIDS, and Donald Francis, MD, PhD, strongly advocated their use to screen blood donors. However, a manuscript by CDC authors Spira et al presenting their data on surrogate testing of blood donors, recommended further study of surrogate tests but stopped short of recommending implementation (Spira, TJ, et al. Unpublished observations, 1984). The article was rejected for publication by *The New England Journal of Medicine* in the summer of 1984, for reasons that are now known.

In the same part of the Report, it is stated that anti-HBc testing of blood donors would have identified 95 percent of those with AIDS, which implies that a similar level of efficacy would have been achieved if all blood donors were screened with anti-HBc. The data did not support such a conclusion. Subsequent studies show that anti-HBc testing might have prevented at most 35 to 40 percent of cases of transfusion transmission.

The Report emphasizes that surrogate testing was not performed because of the cost and the fear of losing donors. But blood bankers were also concerned that, if people believed anti-HBc testing would detect AIDS, they might come to blood centers seeking the test. They feared that those who might not have donated in the absence of surrogate testing might donate if a test were implemented. Thus, implementing surrogate testing might have encouraged risky donors to donate, an outcome that would decrease the possible benefits of testing. Although the concern that surrogate testing might encourage risky donors to donate is mentioned only in passing in the Report, subsequent experience has borne out of its validity. Considerable evidence of HIV test seeking by blood donors has emerged, and the practice continues today.

The Report also skips lightly over the concern that implementing anti-HBc testing might increase the risks of hepatitis B transmission via immune globulin preparations, because antibodies to hepatitis B surface antigen would be removed concomitantly if anti-HBc-positive donations were discarded. This is not entirely a theoretical concern. Hepatitis B has been transmitted by immune globulin preparations in which titers of antibody to hepatitis B surface antigen were very low. More recently, commercial lots of immune globulin that were screened for hepatitis C antibodies have been found to transmit hepatitis C.

Despite the complexity of the decision making and the acknowledgment that no scientific study supported its use, the Report summary finds fault with the decision not to implement surrogate testing.¹⁰²¹

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Ex. 1299, p. 929 (T.F. Zuck and M.E. Eyster, "The Blood Safety Decisions 1982-1986: Perceptions and misconceptions" *Transfusion* October 1996).

D. ANTI-HIV TESTING

1) The Announcement of the Discovery of the Virus: More Questions Than Answers

587. On April 23, 1984, U.S. Secretary of Health, Margaret Heckler, held a widely-reported press conference during which she announced the discovery of the HTLV-III virus and predicted that a test for the virus would be developed within six months.¹⁰²² Many considered that this prediction was unrealistic.¹⁰²³

588. After the announcement of the discovery of the virus, tenders were granted to five companies to develop a test. Such tests were to be evaluated for FDA licensure and efficacy data was to be collected for an undetermined length of time. The CRCS had to look to the United States for its supply of test kits once these were developed. It was aware that these test kits could not be marketed outside the United States before they received FDA approval. In addition, the CRCS expected that manufacturers would give priority of supply to blood banks and testing centres in the United States. This would inevitably cause some delay as test kit manufacturers geared up to produce enough test kits for the United States first, and then across Canada.¹⁰²⁴ In anticipation of these events, the CRCS hoped to participate in the U.S. clinical trial process to gain experience with the test kits before they were formally licensed by the FDA and were available in Canada.

589. Once clinical trials in the United States were under way, the actual implementation of testing was complicated by the fact that there was great uncertainty as to the meaning of a positive test result for antibody to the virus. Many difficult questions were unresolved. Even

¹⁰²² Ex. 634, CRC Vol. 31, Tab I (HHS Press Release, dated April 23, 1984).

¹⁰²³ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30418-30419.

¹⁰²⁴ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28551-28553, 28559-28561; and

Evidence of Dr. Perrault, former National Director BTS, pp. 30441-30442.

if the presence of this antibody signified immunity, no one knew if such an "immune" person was still infectious and could transmit the virus to others.¹⁰²⁵ For example, it was not known whether the presence of the antibody signified immunity to AIDS, or whether a certain proportion of those "infected" persons would actually go on to develop AIDS. There was also a question of whether a co-factor was necessary.

590. When U.S. clinical trials began in July 1984, the New York Board of Health expressed its reluctance to implement the test while the meaning of a positive result was so unclear. This reluctance by the New York Board of Health is significant, given its traditionally progressive public health response, and the fact that it was reported at the time that it had 40% of the AIDS cases in the world.¹⁰²⁶

591. A conference entitled *AIDS, Ethics and the Blood Supply* was convened on January 29 to 30, 1985 in Arlington, Virginia to discuss the complex issues surrounding testing. Attendees included Dr. Derrick, Dr. Gilmore, Dr. Allen, Dr. Zuck and Dr. Tomasulo. While the conference was initially planned to provide the blood banking community with an opportunity to formulate recommendations about the implementation of anti-HIV testing, on January 11, 1985, the PHS issued Provisional recommendations for screening blood and plasma, which predicted that, "tests to detect antibody to HTLV-III will be licensed and commercially available in the United States in the near future to screen blood."¹⁰²⁷ These recommendations stated that all blood ought to be tested and all donors testing repeatedly reactive were to be notified. Accordingly, the focus of the conference changed to a review of the PHS recommendations and

¹⁰²⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 29328-29329, 30940-30942; and Ex. 728B (Plasma Quarterly, Spring 1985, "Information about the Test for Anti-HTLV III Virus", p. 141).

¹⁰²⁶ Evidence of Dr. Davey, former Assistant National Director BTS, p. 30922; and

Ex. 726, p. 3 (CCBC Newsletter, dated September 21, 1984 re: New York State Council on Blood and Transfusion Services Calls Mandated HTLV-III Testing Unjustified at Present and New York State Department of Health New Release, dated July 31, 1984).

¹⁰²⁷ Ex. 558, Vol. 131, Part I, Tab 11 ("v. Donors of Body Fluids and Tissues: Provincial Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome". MMWR, January 11, 1985).

exploration of the areas that the PHS did not adequately address.¹⁰²⁸ For example, the PHS recommendations did not address follow-up of recipients of previous donations made by a positive donor. Uncertainty as to the meaning of a positive test result had widespread ramifications for the blood banking community, such as what to tell donors who tested positive. The test distinguished only between reactive and non-reactive individuals, rather than infected and uninfected individuals. Since there was, as yet, no suitable confirmatory test, many persons would have false positive test results. For this reason, there was concern that healthy donors might refrain from donating because of anxieties about the test. The PHS recommendations further failed to address the possibility that the availability of the test might pose a risk to the blood supply by attracting high-risk donors. Alternative test sites were clearly needed to reduce this risk. A study commissioned by the Irwin Memorial Blood Bank and presented at this conference disclosed that 47% of participants in the study, who were not given any educational material, would donate to get the test. Of those who received information, 10% still indicated they would donate to be tested.¹⁰²⁹

592. At a meeting, a concern regarding the confidentiality of donor records was expressed because of the association of a positive test result with homosexuality. The Canadian gay community was also concerned about confidentiality in the event that positive test results were to be reportable to the public health authorities. Public health authorities were viewed by some as having a poor track record for maintaining confidentiality; accordingly, the gay community was fearful.¹⁰³⁰ Much of the resistance was to 'diagnostic testing'. While

¹⁰²⁸ Ex. 632, CRC Vol. 29, Tab 13 (*Report by Dr. Derrick to Conference on AIDS, Ethics and the Blood Supply, dated January 29 to 30, 1985*).

¹⁰²⁹ Ex. 727 (*CCBC Newsletter, dated February 1, 1985, p. 3*)

¹⁰³⁰ *Evidence of Dr. Klein, physician in private group practice, p. 2769;*

Evidence of Mr. Smith, Halifax CAS Panel, pp. 13226-13227;

Evidence of Ed Jackson and Dale McCarthy, members of AIDS Panel, pp. 23570-23573;

Ex. 585, Vol. 139, Part I, p. 195 (Paper entitled "Until We Know - Choices Facing the Gay Community of Toronto" - Dealing with AIDS Forum, dated 29 June 1983); and

Evidence of Professor Tom Alloway, member of AIDS Panel, p. 23855.

members of the gay community conceded that testing for the purposes of screening blood donations was appropriate, they were also concerned about the confidentiality of donor deferral lists¹⁰³¹ as a positive anti-HIV test was seen by some as tantamount to a proclamation of homosexuality.¹⁰³²

593. A lack of a suitable confirmatory test posed another major problem. The FDA recommendations issued on February 19, 1985 stated that there was no fully standardized confirmatory test available. The Western Blot was still considered to be a research tool, rather than a confirmatory test, as there was no uniform interpretation as to what constituted a positive test result.¹⁰³³ It was recognized that the initial screening ELISA test would need to be extremely sensitive to catch any potentially infected donors; however, the ELISA lacked specificity, with the result that, in a normal donor population there would be many false reactive test results. The Americans resolved this issue by a policy that testing would begin as soon as the first ELISA test kits were licensed. Reactive blood would be discarded. However, notification of donors would await a suitable confirmatory test.¹⁰³⁴ This remained the policy in place after U.S. blood banks began testing in March 1985. The FDA recommendations on May 7, 1985 reiterated that the use of the Western Blot was at the discretion of the collection facility and was not specifically recommended before advising a donor of his or her test results.

¹⁰³¹ Evidence of Dr. Margaret Fast, former Assistant Provincial Epidemiologist and Director, Communicable Disease Control, Community Health Services Division, Manitoba, pp. 10412-10414; and

Evidence of Professor Tom Alloway, member of AIDS Panel, pp. 23864-23865.

¹⁰³² Evidence of Dr. Fast, former Assistant Provincial Epidemiologist and Director, Communicable Disease Control, Community Health Services Division, Manitoba, pp. 10413-10414.

¹⁰³³ Ex. 557, Vol. 130, Tab 7 (FDA Recommendations re: Implementation of PHS Provisional Recommendation, concerning Testing Blood and Plasma for antibodies to HTLV-III, dated February 19, 1985).

¹⁰³⁴ Ex. 558, Vol. 131, Part I, Tab 10 (Goldsmith M., "HTLV-III Testing of Donor Blood Imminent; Complex Issues Remain in JAMA, January 11, 1985").

594. By the time the CRCS began testing in October of 1985, the problems with the Western Blot were largely resolved. Most blood banks were using it as a confirmatory test, despite the fact that it was not actually licensed until 1987.¹⁰³⁵

595. Despite the lack of a suitable confirmatory test and the many concerns voiced at the Hastings Conference in January, 1985, there was a consensus that there be informed consent to test blood donations. Reactive units were to be withdrawn and notification of positive donors was to be delayed pending a suitable confirmatory test, test proficiency, data confidentiality safeguards, donor counselling services, and until more was known about the meaning of a positive test result.¹⁰³⁶

596. While the January 1985 PHS recommendations suggested that testing would begin in the near future, both American blood bankers and the CRCS were taken by surprise on March 2, 1985, when the FDA licensure of the Abbott test kit (the first licensed anti-HIV test kit) was announced:¹⁰³⁷

Although widely publicized by HHS among the national media, the announcement came as a surprise to blood bankers, many of whom received their first notice of the test's approval on the evening news or through a phone call from their local press.¹⁰³⁸

¹⁰³⁵ Ex. 649, CRC Vol. 46, Tab 1 (*Memo from FDA to all registered Blood Establishments re: Recommended Testing Protocol to clarify status of donors with a reactive anti-HIV screening test, dated April 29, 1987*).

¹⁰³⁶ Ex. 632, CRC Vol. 29, Tab 13 (*Report by Dr. Derrick on the Conference on AIDS, Ethics and the Blood Supply, dated January 29 to 30, 1985*).

¹⁰³⁷ *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30949-30951.*

¹⁰³⁸ Ex. 727 (*CCBC Newsletter, dated March 4, 1985, p. 3*).

2) The CRCS Involves NAC AIDS Because of Strained Relations with CBC

597. While it was anticipated that anti-HIV testing would be implemented in the United States in 1985, the CRCS was unaware when this would occur. Nonetheless, it had commenced making preparations for its own testing program before the announcement in the United States that the FDA had licensed the first test kits in early March 1985. On August 2, 1984, Dr. Derrick wrote to Dr. Perrault alerting him of the problems inherent in the test, and recommending that the CRCS be prepared to implement testing in 1985. He suggested that NAC AIDS be approached to help formulate a plan to, among other things, test high-risk individuals so that they did not attend CRCS blood donor clinics for testing.¹⁰³⁹ The CRCS was not requesting assistance from NAC AIDS about whether or when to begin testing, but rather how it should be done.¹⁰⁴⁰

598. The CRCS kept the CBC informed of its intention to implement anti-HIV testing as soon as test kits were available in Canada. As early as September, 1984, the CRCS informed the CBC through its 1985 proposed blood program budget, that it might be necessary to bring the issue of implementing testing to the CBC sometime during 1985. The CRCS submitted, through its 1985 budget request, an allowance in the NRL hepatitis section budget for a preliminary evaluation of such tests. There was no allowance in the 1985 budget for the adoption of a definitive test, since there was no certainty as to when one would be available, nor was there information about possible costs.¹⁰⁴¹

599. At the October 9, 1984 meeting of NAC AIDS, Dr. Gill reported on the results of LCDC diagnostic testing, which had begun in July of 1984 using an in-house test kit. Attendees at that meeting recognized the importance of the medical, legal, and sociological issues which would later be raised at the Hastings Conference. It was agreed that until these

¹⁰³⁹ Ex. 627, CRC Vol. 24, Tab 35 (*Memo from Dr. Derrick to Dr. Perrault, dated August 2, 1984*).

¹⁰⁴⁰ Evidence of Dr. Shepherd, NAC AIDS Panel, pp. 24877-24878.

¹⁰⁴¹ Ex. 736, Tab 41, p. 4 (*The Red Cross Society Blood Program Budget, 1985 proposed budget III: Program Overview*).

issues were resolved, no specific action would be taken to test blood donations in Canada. Dr. Gilmore, Chair of NAC AIDS, suggested that a task force be struck to deal with this issue. It was decided that the CRCS not introduce screening until the *ad hoc* committee reported back.¹⁰⁴² Neither the CRCS, nor the members of NAC AIDS, expected that this would stop the CRCS from making plans to implement anti-HIV testing or from evaluating test kits as they became available in Canada.¹⁰⁴³

600. NAC AIDS's cooperation was necessary for an additional reason. The CRCS was not the only player involved in the implementation of anti-HIV testing. Testing for anti-HIV was expected to have widespread implications for the healthcare system and would have a cross-country impact. Responsibility for all these factors outside the blood system lay with provincial public health authorities. There would have to be diagnostic testing offered at alternative test sites outside the CRCS so that high-risk groups would not be tempted to attend blood donor clinics for testing. As provincial public health authorities did not appear to be engaged in setting up alternative test sites, the CRCS wanted to raise awareness of this issue to motivate the provinces into action, which it perceived must be done immediately.¹⁰⁴⁴

601. NAC AIDS was the only federal committee which was dealing with AIDS. While it was common in other countries for national public health authorities to direct that certain action be taken in response to AIDS, no one from Health and Welfare Canada (LCDC or BoB) had appeared to have taken a leadership role. There appeared to be no existing national public health structure, which could address these issues, except NAC AIDS.¹⁰⁴⁵

¹⁰⁴² Ex. 684, Vol. 148, Tab D18, p. 10 (*Minutes of NAC AIDS Meeting, dated October 9, 1984*).

¹⁰⁴³ Evidence of Dr. Shepherd, *NAC AIDS Panel*, p. 24890; and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28546-28556, 30965-30973; and

Evidence of Dr. Clayton, *NAC AIDS Panel*, pp. 41675-41676, 41689-41690.

¹⁰⁴⁴ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28681-28683; and

Evidence of Dr. Perrault, former National Director BTS, pp. 28680-28683, 30942-30943.

¹⁰⁴⁵ Evidence of Dr. Perrault, former National Director BTS, pp. 27534-27537, 28077-28079, 30420-30423, 30425-30427.

602. The CBC had access to the deliberations and developments of NAC AIDS and the CRCS plans for testing through Dr. Leclerc-Chevalier's membership on that committee. Dr. Clayton assumed that she was keeping the CBC informed of NAC AIDS discussions and decisions.¹⁰⁴⁶

603. The CRCS recognized that in order to implement anti-HIV testing as soon as possible, it would be necessary to meet the high level of scrutiny always given to its budget submissions. It needed sufficient political and scientific backing to capture the attention of the CBC,¹⁰⁴⁷ as safety issues which required funds received the same level of scrutiny as did all other parts of the blood program.¹⁰⁴⁸

604. The CRCS believed that it was important to use the political clout and expertise of NAC AIDS, particularly its epidemiological expertise, in order to bolster its case to the CBC for timely implementation of anti-HIV testing.¹⁰⁴⁹ Experience had shown that in order to convince the CBC to commit to a large recurring expenditure, it needed to build a strong case. While NAC AIDS was merely an advisory body and could not bind either the CRCS, the provincial or the federal governments, or the CBC, it did carry moral suasion.¹⁰⁵⁰ Dr. Gilmore, who sat on NAC AIDS, was a well-known expert who added to the credibility of the CRCS's request for urgent consideration of the testing program.¹⁰⁵¹

¹⁰⁴⁶ Evidence of Dr. Clayton, *NAC AIDS Panel*, p. 41926.

¹⁰⁴⁷ Evidence of Dr. Perrault, former National Director BTS, pp. 28865-28872.

¹⁰⁴⁸ Evidence of Mr. Klotz, former member of CBC Advisory Sub-Committee, p. 36848.

¹⁰⁴⁹ Evidence of Dr. Perrault, former National Director BTS, pp. 28077-28079.

¹⁰⁵⁰ Evidence of Dr. Perrault, former National Director BTS, pp. 30425-30427.

¹⁰⁵¹ Evidence of Dr. Perrault, former National Director BTS, pp. 30467-30468; and

Evidence of Mr. Langley, former member of the CBC Advisory Sub-Committee, pp. 36436-36437.

605. On December 11, 1984, Dr. Leclerc-Chevalier advised the CBC Executive Committee that the CBC might be requested to approve testing of blood for HIV antibodies in 1985, at a cost of \$5 million or \$10 million if two tests were implemented.¹⁰⁵²

606. In January 1985, the NAC AIDS Epidemiology and Public Health Subcommittee contemplated CRCS testing and the various preliminary complex issues which would have to be resolved.¹⁰⁵³

607. While the full membership of the CBC met on January 15 and 16, 1985, no discussion on the issue of anti-HIV testing appears in the Record of Decisions. Nor does there appear to be any update from Dr. Leclerc-Chevalier on the activities of NAC AIDS. The primary purpose of this meeting appears to have been to review the proposed CRCS Blood Program Budget and to consider the CRCS National Office relocation.¹⁰⁵⁴ This proposed budget did not include a contingency budget request for testing, as contingency budgets were never considered by the CBC. The CRCS was not invited to attend this meeting and, in keeping with the custom of the CBC, the minutes of this meeting were not forwarded to the CRCS.¹⁰⁵⁵

608. On January 22, 23, and 24, 1985, members of the CBC Secretariat met with CRCS staff to receive further justification on the proposed BTS budget, including items not finally approved by the CBC.¹⁰⁵⁶ The Secretariat informed the CRCS that a number of staff

¹⁰⁵² Ex. 860, Vol. 192, Tab 4, p. 152 (*Record of Decisions of the Canadian Blood Committee Executive Committee Meeting, December 11, 1984*).

¹⁰⁵³ Ex. 1214, p. 3 (*Minutes, NAC AIDS Epidemiology and Public Health Subcommittee, dated January 9, 1985, paragraph 6*); and

Ex. 1238 (*Draft NAC AIDS Position Paper, Epidemiology and Public Health Subcommittee, dated January 3, 1985*).

¹⁰⁵⁴ Ex. 860, Vol. 192, Tab 6, (*Draft Record of Decisions of meeting of the Canadian Blood Committee, January 15 - 16, 1985*).

¹⁰⁵⁵ *Evidence of Dr. Perrault, former National Director BTS, p. 30603.*

¹⁰⁵⁶ Ex. 860, Vol. 192, Tab 7 (*Minutes of a Budget Working Session with members of the Secretariat held on January 22, 23 and 24, 1985*).

positions requested by the CRCS had not been approved. Additional justification was required for several other proposed positions.¹⁰⁵⁷ During this session the CRCS was required to justify its request for items as small as a 0.5 Data Entry Clerk, full-time equivalent.¹⁰⁵⁸ This justification for a 0.5 Data Entry Clerk in Toronto required an additional two-page written document submitted to the CBC.¹⁰⁵⁹ This was typical of the scrutiny the CBC gave CRCS budget requests.

609. After the Secretariat thanked the CRCS officials for meeting with it on short notice, the minutes indicate that CRCS staff were advised of the following:

2. Mme. Boutet indicated that the 1985 budget would be held at a maintenance level and that the CRCBTS was to justify additions/priorities in excess of provincial guidelines.
3. Mme. Boutet mentioned that the Committee would like to be advised of circumstances that cause overexpenditures before they happen or action is taken¹⁰⁶⁰

610. At the same meeting, the CRCS requested whether staff could be recruited for a new position prior to the receipt of the approved budget. The next day, on January 25, 1985, the CRCS was informed by the Secretariat that staff should not be recruited prior to receipt of the approved budget.¹⁰⁶¹ The CRCS was clearly advised that expenditures of any kind were not to be made prior to final approval. Formal transmittal by the CBC of the approved budget

¹⁰⁵⁷ Ex. 860, Vol. 192, Tab 7, p. 194 (*Minutes of a Budget Working Session with members of the Secretariat held on January 22, 23 and 24, 1985*).

¹⁰⁵⁸ *Ibid.*, p. 194.

¹⁰⁵⁹ Ex. 957, Vol. 288, Tab 17, p. 278-279 (*Toronto Centre Laboratory Staffing Justification 1985 Budget Submission, February 7, 1985*).

¹⁰⁶⁰ Ex. 860, Vol. 192, Tab 7, p. 193 (*Minutes of a Budget Working Session with members of the Secretariat held on January 22, 23 and 24, 1985*).

¹⁰⁶¹ Ex. 860, Vol. 192, Tab 7, p. 198 (*Minutes of a Budget Working Session with the members of the Secretariat, January 22, 23 and 24, 1985*).

was not made until February 20, 1985.¹⁰⁶² The negotiation of the 1985 budget was typical of relations between the CRCS and the CBC.

3) U.S. Information Embargo

611. By the November 2, 1984 BTS Advisory Committee meeting, the CRCS was in contact with three of the five American manufacturers to discuss evaluating their test kits for use in Canada.¹⁰⁶³ While the CRCS had clearly decided to evaluate all the test kits by January 1985,¹⁰⁶⁴ Abbott was the only manufacturer which agreed to provide its test kit for CRCS evaluation. It did not do so until February.¹⁰⁶⁵ The Abbott test kit was evaluated from February 5 to 19, 1985. The pre-market evaluation involved 3,000 blood samples, which were unlinked to donors, as required in the standard contract with Abbott.¹⁰⁶⁶ This test performed well and was all the more suitable because it used the same technique and equipment as the Abbott hepatitis test kit that the CRCS was already using.¹⁰⁶⁷ The CRCS test results were incorporated into the data sent to the FDA for licensing.¹⁰⁶⁸

:1062 *Ex. 736, Tab 44 (Letter from Dr. Leclerc-Chevalier to Mr. Weber, February 20, 1985).*

:1063 *Ex. 629, CRC Vol. 26, Tab 27 (Minutes of BTS Advisory Committee meeting, dated November 2, 1984).*

:1064 *Ex. 719 (Minutes of General Staff Meeting, Hepatitis Section, dated January 21, 1985).*

:1065 *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28548-28551.*

:1066 *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28655-28659, 29331-29335, 31024-31027; and*

Ex. 749 (Group of Documents re: Requirement of Unlinked Samples).

:1067 *Ex. 696, Tab 1 (Memo from Caroline Archibald to Barbara Buchner, dated February 21, 1985 re: Abbott Anti-HTLV III Kit Evaluation).*

:1068 *Evidence of Dr. Clayton, NAC AIDS Panel, p. 41699; and*

Evidence of Dr. Davey, former Assistant National Director BTS, p. 29334.

612. However, because the purpose was simply to evaluate the test,¹⁰⁶⁹ the data generated could not be used to generalize the seroprevalence of HIV in the general donor population for several reasons. First, the predictive value of the screening test could only be determined once the prevalence of HIV in the general donor population was known.¹⁰⁷⁰ Secondly, the prevalence of disease could only be determined using a much larger sample size, as there is known to be a high error rate with such small studies.¹⁰⁷¹ Thirdly, these results were not validated with a satisfactory confirmatory test since the confirmatory test available at the time was poor and was never licensed by the FDA.¹⁰⁷² Fourthly, there was always a greater false positive rate in a low prevalence population, such as blood donors, given the sensitivity of the test.¹⁰⁷³ Finally, even if the samples were confirmed, it was known that multi-parous women make antibodies against their children so that they were more likely to set off an indeterminate Western Blot test.¹⁰⁷⁴

613. Before March 1985, the CRCS contacted the head offices of all five U.S. test kit manufacturers for the purpose of receiving test kits to evaluate. Other test kit manufacturers were not interested in having the CRCS evaluate their test kits because, in the past, there had been no licensing requirement for test kits to be introduced into Canada. Test kits had traditionally been approved for use in Canada based on FDA approval.¹⁰⁷⁵ Unfortunately, this decision by the manufacturers and an unexpected prohibition on the release of test kit evaluation data by the NIH left the CRCS without any information about any of the test kits, other than

¹⁰⁶⁹ Ex. 696, Tab 1 (*Memo from Caroline Archibald to Barbara Buchner, dated February 21, 1985 re: Abbott Anti-HTLV III Kit Evaluation*); and

Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 10, 1996, p. 239.

¹⁰⁷⁰ *Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 10, 1996, pp. 211-212.*

¹⁰⁷¹ *Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 10, 1996, p. 224.*

¹⁰⁷² *Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 10, 1996, pp. 230-231.*

¹⁰⁷³ *Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 11, 0996, pp. 233-235.*

¹⁰⁷⁴ *Evidence of Dr. O'Shaughnessy in CRCS ats Walker/Osborne, dated October 10, 1996, pp. 246-247.*

¹⁰⁷⁵ *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28546-28550, 28604.*

Abbott's, until they were licensed by the FDA in March of 1985. It was expected that data from the FDA clinical trials of all the test kits would be discussed at a conference attended by Dr. Barbara Buchner in Bethesda on November 25 to 28, 1984. The CRCS had hoped that this information would allow it to begin making plans to evaluate the most promising ones. However, at the last minute, disclosure of this data was prohibited by the NIH.¹⁰⁷⁶ It was fortuitous for the CRCS that Abbott was the first test kit licensed by the FDA on March 2, 1985.

614. By that time, the CRCS had decided to contract with Abbott as the initial supplier of test kits because its evaluation was favourable and AmCross had also chosen the Abbott test kit. Accordingly, the information embargo, the fact that the CRCS was able to evaluate only the Abbott kit before March, and the lack of a suitable confirmatory test, did not affect the ability of the CRCS to implement testing as soon as possible.

615. On April 12, 1985, Barbara Buchner, Section Head, Hepatitis, National Reference Laboratory attended the AmCross National Office to discuss the results of its evaluations of the various test kits. This was the first time that the CRCS had access to the results from AmCross's clinical trials of the various test kits.¹⁰⁷⁷ AmCross had chosen the Abbott test kit because it was as good or better than any other. This decision provided some comfort to the CRCS, which had only had the opportunity to evaluate the Abbott and Dupont test kits. The latter test was still unlicensed and considered by the CRCS to be unacceptable.^{1078,1079}

¹⁰⁷⁶ Ex. 631, CRC Vol. 28, Tab 14 (*Trip Report by Barbara Buchner to attend "AIDS Update - Action for Public Health" Conference from November 25-28, 1984*).

¹⁰⁷⁷ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28675-28676.

¹⁰⁷⁸ Ex. 634, CRC Vol. 31, Tab 13 (*Trip Report from Barbara Buchner to AmCross, dated April 12, 1985*).

¹⁰⁷⁹ Ms. Buchner later reported on the results of the evaluations of the other test kits - for Dupont on March 21, 1985; Ortho on May 28, 1985; and Travenol on May 31, 1985.

Ex. 719 pp. 4-6 and 10-14 (*Minutes of General Staff Meeting, Hepatitis Section, National Reference Laboratory*).

616. As soon as the Abbott test kit was licensed, test kits were immediately distributed throughout the United States. Because there was an insufficient number of test kits initially, blood centres were given priority. The first U.S. centres were supplied with enough test kits to test incoming donations, but inventory remained untested.¹⁰⁸⁰ Until there was adequate supply, blood centres at the highest risk areas received test kits first. It was not until mid-summer that almost all United States blood banks were testing for anti-HIV.¹⁰⁸¹

4) Task Force on AARV Testing: BMD Pre-Market Approval Required

617. On March 4, 1985, the CRCS advised all Medical Directors that it was in the process of evaluating test kits. Dr. Perrault wrote that,

...the decision to test blood donors for AIDS is the responsibility of the Department of Health and Welfare, which will consider recommendations from National Advisory Committee on AIDS and its special task force on AIDS testing.

The Canadian Red Cross Society, ... will be making its recommendations through those bodies.¹⁰⁸²

The memo further warned that uniform testing in Canada could be delayed for "logistical reasons".¹⁰⁸³ By this Dr. Perrault meant that it was anticipated that there would be a shortage in supply of test kits in Canada initially as the manufacturers geared up to produce a sufficient supply.¹⁰⁸⁴ In order to begin testing as soon as possible, the CRCS considered staged

¹⁰⁸⁰ *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22559.*

¹⁰⁸¹ *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22463-22466.*

¹⁰⁸² *Ex. 632, CRC Vol. 29, Tab 40 (Memo from Dr. Perrault to Medical Directors et al, dated March 4, 1985).*

¹⁰⁸³ *Ibid.*

¹⁰⁸⁴ *Evidence of Dr. Perrault, former National Director BTS, pp. 30441-30442.*

implementation, with the first tests being conducted at blood centres in the urban areas most greatly affected by AIDS.¹⁰⁸⁵

618. This possibility was discussed at the March 7, 1985 meeting of the Task Force on AIDS-Associated Retrovirus (AARV) Testing, which had been struck at the October 9, 1984 NAC AIDS meeting. Members and attendees of the task force included: Dr. Mathias; Kim Elmslie; Dr. Clayton; Dr. Coates; Dr. Davey; Dr. Furesz; Dr. Jessamine; Dr. O'Shaughnessy; Dr. Gilmore; and Dr. Leclerc-Chevalier.¹⁰⁸⁶ This was the first and only meeting of this task force and was held only days after the first two test kits were licensed by the FDA. Had this March 1985 task force meeting been scheduled earlier, it would not have been as productive because of the NIH information embargo imposed upon clinical trial data until FDA licensure. The task force generated recommendations, not only on screening of blood donations, but also on diagnostic testing. It was clear to everyone at the meeting that anti-HIV testing had ramifications which went beyond the domain of the CRCS.¹⁰⁸⁷

619. One of the major issues discussed at this meeting was the need for the provincial health authorities to set up alternative test sites prior to CRCS testing.¹⁰⁸⁸ Although the CRCS was already making preparations to introduce a screening test, the provincial health authorities were not taking such steps. As it was desirable that the CRCS begin testing as soon as possible, the CRCS made it clear that it would not delay *testing* until alternative test sites were in place. Rather, it would delay *notification* of donors of their positive test results until alternative test

¹⁰⁸⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28617-28618.

¹⁰⁸⁶ Ex. 632, CRC Vol. 29, Tab 41 (Minutes of Meeting, Task Force on AIDS-Associated Retrovirus Testing in Canada, dated March 7, 1985).

¹⁰⁸⁷ Evidence of Dr. Gilmore, former NAC AIDS member, pp. 24884-24886; and

Evidence of Dr. Frances Shepherd, former NAC AIDS member, pp. 24891-24892.

¹⁰⁸⁸ Ex. 632, CRC Vol. 29, Tab 41, p. 5 (Minutes of Meeting, Task Force on AIDS-Associated Retrovirus Testing in Canada, dated March 7, 1985).

sites were in place.¹⁰⁸⁹ The need for alternative test sites prior to notifying donors of their test results was well recognized. There was a very real concern by blood bankers, supported by evidence from studies, that providing testing only at blood centres would jeopardize the safety of the blood supply. High-risk donors would come to blood donor clinics to be tested, because there was nowhere else to go and confidentiality was assured.¹⁰⁹⁰ The CRCS was aware of the data supporting this, which had been presented at the Hastings Conference, and was further aware that some donors occasionally attended at blood donor clinics to be tested for syphilis.¹⁰⁹¹ In July of 1985, at the anti-HTLV-III testing workshop in Bethesda, Maryland, it was reported that 30% of persons appearing at alternative test sites stated that they would have donated blood had alternative test sites not been available.¹⁰⁹²

620. This was the first warning provided by a national committee to provincial health authorities that alternative test sites would be required in the near future. Although there was provincial and federal public health authority representation on the Task Force on AARV Testing, Dr. Leclerc-Chevalier also attended as an observer, being the CBC representative. It is unclear what further steps were taken by the attendees of the task force meeting to inform the provincial health ministries or the CBC of this pressing issue.

¹⁰⁸⁹ Evidence of Dr. Perrault, former National Director BTS, and Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28693-28694.

¹⁰⁹⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22661-22662; Evidence of Dr. Dale McCarthy, member of AIDS Panel, pp. 23570-23573, 23617-23622; Evidence of Professor Tom Alloway, member of AIDS Panel, pp. 23617-23622, 23858; and Evidence of Dr. Perrault, former National Director BTS, and Dr. Davey, former Assistant National Director BTS, pp. 28691-28692.

¹⁰⁹¹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28691-28692; and Ex. 634, CRC Vol. 31, Tab 27 (Minutes of the National BTS Advisory Committee meeting, dated April 26, 1985, p. 5, paragraph 22).

¹⁰⁹² Ex. 746, Tab 15 (Trip Report from Barbara Buchner to attend the Anti-HTLV-III Workshop in Bethesda, Maryland on July 31, 1985, p. 10).

621. Dr. MacDonald, of the Legislative and Regulatory Affairs Environmental Health Directorate, was an invited guest to the task force meeting and announced that the Bureau of Medical Devices (hereinafter referred to as "BMD") pre-market approval would be required before the test kits could be distributed for use in Canada. This announcement was made without prior notice to the CRCS, and only a few days after notice had been given to the American test kit manufacturers. LCDC estimated that it would need one week to evaluate each of the test kits which had been FDA licensed. The soon-to-be-enacted regulations would give the BMD 60 days to either reject or approve each test.¹⁰⁹³ Dr. Davey, the CRCS representative at the task force meeting, convinced the LCDC to allow the CRCS to assist in its evaluations, which the CRCS believed would further expedite the process in Canada.¹⁰⁹⁴

622. This licensing requirement was unprecedented and unexpected.¹⁰⁹⁵ Previously, test kits had been accepted for use in Canada based on FDA licensing¹⁰⁹⁶. The restriction was felt to be appropriate because of the uncertainties surrounding the test and the psychosocial implications. LCDC wanted to ensure proper quality control by those utilizing the test and therefore wanted to restrict its use to designated laboratories only.¹⁰⁹⁷ While Dr. Davey agreed that regulation by the BMD was necessary for diagnostic purposes, he did not agree that it was necessary for screening blood donations.¹⁰⁹⁸

¹⁰⁹³ Ex. 632, CRC Vol. 29, Tab 41, p. 3 (*Minutes of Meeting, Task Force on AIDS-Associated Retrovirus Testing in Canada, dated March 7, 1985*).

¹⁰⁹⁴ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28608-28612; and

Ex. 632, CRC Vol. 29, Tab 41 (*Minutes of Meeting, Task Force on AIDS-Associate Retrovirus Testing in Canada, dated March 7, 1985, recommendation no. 3*).

¹⁰⁹⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28609-28612.

¹⁰⁹⁶ Evidence of Dr. Davey, former Assistant National Director BTS, p. 28604.

¹⁰⁹⁷ Evidence of Dr. Gilmore, former NAC AIDS member, pp. 24941-24942; and

Evidence of Dr. Mathias, former NAC AIDS member, pp. 24939-24940.

¹⁰⁹⁸ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28608, 30443-30445, 30959-30960.

623. As of April 25, 1985, only Abbott had applied to the BMD for pre-market approval of its test kit.¹⁰⁹⁹ But for the requirement of BMD approval, the test kits might have been available in Canada for sale in April or May of 1985.¹¹⁰⁰ Even if supplies were insufficient for full-scale national implementation, the CRCS would have been able to undertake a staged implementation, beginning with the highest risk centres, after which there would presumably have been a sufficient number of test kits to implement testing across the country. In any event, because CBC approval did not come until much later, test kits were in sufficient supply and there was no need to proceed by way of staged implementation.¹¹⁰¹

624. Among the Task Force on AARV recommendations to the CRCS on March 7, 1985, was that the CRCS develop an implementation plan for screening blood donations for submission to NAC AIDS by April 30, 1985.¹¹⁰²

625. On April 15, 1985, Dr. Perrault informed the CBC Advisory Sub-Committee that the CRCS was developing an implementation plan for testing blood and plasma donations for the presence of the HIV antibody. He further stated that, in addition, the NAC AIDS task force on AARV would present its recommendations to the meeting of NAC AIDS on May 15, 1985. In turn, these NAC AIDS recommendations would be presented to the CBC at its next meeting.¹¹⁰³ Dr. Perrault also took this opportunity to review the CRCS draft implementation plan with the CBC Advisory Sub-Committee¹¹⁰⁴ Present at this meeting was the New Brunswick representative of the CBC, Dr. Ingraham, who was also Chair of the Advisory Sub-

¹⁰⁹⁹ Ex. 743, Tab 11 (*Memo from Dr. Clayton to Dr. Liston, dated April 24, 1985*).

¹¹⁰⁰ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27068-27070.

¹¹⁰¹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28645-28650.

¹¹⁰² Ex. 632, CRC Vol. 29, Tab 41 (*Minutes of Meeting, Task Force on AIDS-Associated Retrovirus Testing in Canada, dated March 7, 1985 - recommendation no. 1*).

¹¹⁰³ Ex. 860, Vol. 192, Tab 9, p. 216 (*Draft Record of Decisions, Sixth Meeting of the Advisory Sub-Committee to the Canadian Blood Committee, April 15, 1985*).

¹¹⁰⁴ Ex. 860, Vol. 192, Tab 10, p. 268 (*Note to file by Dr. D. Leclerc-Chevalier, April 16, 1985*).

Committee, and the entire CBC Secretariat.¹¹⁰⁵ Consequently, the CBC was kept informed about all developments and the imminence and importance of the CRCS testing was reiterated.

626. On April 17, 1985 the Executive Committee of the CBC met. Dr. Leclerc-Chevalier informed the committee that since the CBC meeting in January 1985, NAC AIDS had appointed a Task Force (AARV) on HIV testing. (This was incorrect. In fact, the task force had been appointed in October, 1984, but had not met until March 1985).¹¹⁰⁶ The Executive Committee was advised that recommendations for diagnostic testing and screening blood donations were developed at the task force meeting and that it was recommended that the CRCS develop an implementation plan for anti-HIV testing to be presented by April 30, 1985 for consideration by NAC AIDS at its May 15, 1985 meeting.¹¹⁰⁷

627. It is clear from these minutes that the CBC recognized its ultimate responsibility for approval of anti-HIV testing of blood donations and were aware of the imminence of this matter. The CBC knew that testing was a multi-million dollar expense and that the CRCS would require budget approval to proceed. There was no indication that the CBC members took any action to expedite the process.¹¹⁰⁸

628. During this meeting, it was noted that the CBC Executive felt that it was inappropriate for the CRCS to make any announcement on issues related to the blood program

¹¹⁰⁵ Ex. 860, Vol. 192, Tab 9, p. 211 (*Draft Record of Decisions, Sixth Meeting of the Advisory Sub-Committee to the Canadian Blood Committee, April 15, 1985*).

¹¹⁰⁶ Ex. 684, Vol. 148, Tab D18 (*Minutes of NACAIDS Meeting, dated October 9, 1984, p. 10*); and
Ex. 632, CRC Vol. 29, Tab 41 (*Minutes of Meeting of Task Force on AARV Testing, dated March 7, 1985*).

¹¹⁰⁷ Ex. 860, Vol. 192, Tab 10, p. 246 (*Record of Decisions of the Meeting of the Executive Committee of the CBC, April 17, 1985*).

¹¹⁰⁸ *Evidence of Mr. Stephen Dreezer, Member of the CBC, p. 35912.*

prior to discussion with the CBC.¹¹⁰⁹ This discussion was sparked by an article in the April 15, 1985 edition of the *Globe and Mail*, which stated:

The Canadian Red Cross will begin testing the blood it gets from donors this summer for evidence of the AIDS virus. The tests, likely to cost \$10 million a year, are similar to those recently introduced in U.S. blood banks.¹¹¹⁰

629. The following day when Dr. Perrault was called upon to explain, Dr. Leclerc-Chevalier made the following note:

Mr. Stephen Dreezer, Director General of Finance, Ontario Ministry of Health, called Dr. Leclerc-Chevalier's office on April 16 and in the presence of Dr. Perrault complained about this article. The situation was explained to Mr. Dreezer, i.e. that the Red Cross had made no such statement and referred him to the Task Force recommendation whereby the Red Cross is to present an implementation plan to the Task Force of the National Advisory Committee on AIDS. Dr. Perrault further informed Mr. Dreezer that the implementation plan was read to the CBC Advisory Sub-Committee and it was made very clear at that point that this was a draft only, and required further review by the Advisory Committee of the Blood Transfusion Service of the Red Cross and by the National Advisory Committee on AIDS to the Bureau of Biologics and Medical Devices for appropriate regulatory authorization to proceed and to the CBC for appropriate funding.

Mr. Dreezer understood the mechanisms but nevertheless felt strongly that his Deputy Minister, Gerard Raymond, took a dim view of such a statement in the press...¹¹¹¹

5) The CRCS Implementation Plan

630. Following the March 7, 1985 meeting of the Task Force on AARV Testing, the CRCS took steps to formulate the necessary plans for the implementation of testing across the country. A Preliminary BTS Implementation Plan was drafted by Dr. Harding at NRL by

¹¹⁰⁹ Ex. 860, Vol. 192, Tab 10, p. 249 (*Record of Decisions of the Meeting of the Executive Committee to the CBC, April 17, 1985*).

¹¹¹⁰ *Ibid.*, p. 270 (*The Globe and Mail*, April 15, 1985).

¹¹¹¹ *Ibid.*, pp. 268 and 269 (*Note to File by Dr. D. Leclerc-Chevalier, April 16, 1985*).

March 22, 1985 and presented to the Medical Directors Committee, which met three days later. It recognized the main steps that NRL would be required to take in order to prepare for implementation: additional equipment and staff would be required; test kits would have to be evaluated; a supplier would have to be selected; and NRL staff would have to train centre staff to use the test.¹¹¹² A preliminary budget, including centre costs was prepared by April 2, 1985.¹¹¹³

631. By April 24, 1985, on the assumption that there would be timely approval of testing, CRCS National office had reserved a time (July 29 and 30, 1985) and location for a training workshop for senior technicians at all blood centres on HIV test procedures. Staff were notified that they were to be available these days.¹¹¹⁴ Medical Directors were advised of this training seminar by way of a telex from Pat Humphreys dated April 26, 1985.¹¹¹⁵ This telex advised that there was a "strong possibility" that the CRCS would begin testing in the near future. Details were not expected to be available until after April 30, 1985, when the CRCS was to submit its implementation plan to NAC AIDS.

632. By April 25, 1985, the CRCS had completed the next draft of a feasibility plan for implementation of testing in centres. This plan provided for a start-up date of August 5, 1985, if program approval was immediately forthcoming. This would mean full conversion by early September.¹¹¹⁶

¹¹¹² Ex. 633, CRC Vol. 30, Tab 19, pp. 66167-66169 (*Preliminary BTS Implementation Plan of Screening for all Donor Blood and plasmas for Anti-HTLVIII*, dated March 22, 1985 by R.Y. Harding).

¹¹¹³ Ex. 743, Tab 9 (*Memo from Sadan Mankikar to Dr. Harding, dated April 2, 1985*).

¹¹¹⁴ Ex. 746, Tab 7 (*Telex from Pat Humphreys to all Medical Directors and Technical Supervisors, dated April 24, 1985*).

¹¹¹⁵ *Ibid.*

¹¹¹⁶ Ex. 746, Tab 8 (*Memo from Pat Humphreys to Dr. Davey, dated April 25, 1985 enclosing Feasibility Plan*); and

Ex. 634, CRC Vol. 31, Tab 27 (CRCS Response to the Recommendations of the Task Force on AARV Testing).

633. Based on its evaluations of the Abbott test kit and the fact that this was the kit chosen for use in both the United States and Australia, the CRCS pre-empted the usual tender process for selecting test kits in order to save time.¹¹¹⁷ By May 1, 1985, the CRCS had made all the preparations it could without CBC approval and was ready to begin the implementation process immediately. However, since no test kit had yet received BMD approval in Canada, the CRCS utilized this time to evaluate other test kits.

634. The CRCS Implementation Plan was submitted to NAC AIDS on May 1, 1985.¹¹¹⁸ The plan provided a 10-to-12 week estimate as to when full conversion could take place. It assumed that approval would be immediately forthcoming, and therefore estimated a start-up date of the beginning of August. By way of comparison, the AmCross implementation schedule reviewed by Barbara Buchner when she visited AmCross in April 1985 provided for a 35-day phase-in period. This is comparable to the period between CRCS staff training and full conversion, also about 35 days. Because AmCross had participated in test kit clinical evaluations for FDA licensing, it had already determined which test kits were most suitable and many Centres already had the necessary equipment in place and staff trained to conduct the test, before FDA licensure. By chance, the technical staff at AmCross had already organized a meeting at the time of FDA licensure and they were available on short notice to undergo training in performing the new test. The AmCross 35-day countdown started at the time of its meeting for technical staff.¹¹¹⁹ Thus, at the time of FDA licensure, AmCross was further along than the CRCS was when the CBC approved its testing program. Until CBC approval, the CRCS could not contract with Abbott, although it had already chosen the Abbott test kit by the end of April based on its own results and the fact that it was the test of choice in Australia and the U.S. Nor could the CRCS order equipment, begin the renovations necessary in some centres to

¹¹¹⁷ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28702-28704, 28554-28556.

¹¹¹⁸ Ex. 685, Vol. 149, Tab 14 (Letter from Dr. Perrault to Dr. Clayton re Implementation of Screening for AIDS-Associated Retrovirus).

¹¹¹⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28707-28713; and

Ex. 681, Vol. 145, Tab 14 (Minutes of the National BTS Advisory Committee, dated April 26, 1985).

accommodate the equipment required for another test, or commence staff training without further equipment.

635. This analysis shows that the CRCS and AmCross had a similar interval between training and full conversion. The additional 3 to 5 weeks required by the CRCS was to allow for contracting with Abbott, receiving the first supplies of test kits, ordering equipment, hiring staff, and renovating some centres. The CRCS time frame compares favourably with the time taken in the U.S. between licensing and the time virtually all blood banks across the United States were testing.¹¹²⁰ Some U.S. centres which had conducted clinical trials for FDA licensing purposes were ready to go ahead as soon as test kits were available, while others needed to make preparations to be ready. While most blood centres across the U.S. were testing by mid-summer,¹¹²¹ in Canada funding approval was only obtained on August 1, 1985. Testing started in late September and the entire hospital and CRCS inventory in Canada was fully converted by November 4, 1985.

636. On April 26, 1985, the CRCS Response to the Recommendations on the AARV Task Force Meeting was tabled at the BTS Advisory Committee meeting and approved as the basis for CRCS policy.¹¹²² At the May 15, 1985 NAC AIDS meeting, the CRCS Implementation Plan was considered and approved.¹¹²³ This plan was formally submitted to the CBC on May 17, 1985. The CBC did not discuss the CRCS testing program until its regular meeting on June 4 and 5, 1985. While more timely approval would have allowed for complete conversion by the first week in September, 1985, the CBC did not make any efforts to expedite the process.¹¹²⁴

¹¹²⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22556-22558.

¹¹²¹ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22463-22466.

¹¹²² Ex. 634, CRC Vol. 31, Tab 27 (Minutes, BTS Advisory Committee Meeting of April 26, 1985).

¹¹²³ Ex. 635, CRC Vol. 32, Tab 14, p. 7 (Minutes of NAC AIDS Meeting, dated May 15, 1985).

¹¹²⁴ Ex. 635, CRC Vol. 32, Tab 22 (Handwritten timeline drawn by RAP at NAC AIDS meeting); and Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28729-28736.

637. Dr. Perrault raised the issue of the necessity of alternative test sites at the NAC AIDS May 15, 1985 meeting as the provinces had not yet taken any preparatory steps. NAC AIDS struck a Task Force on Alternative Test Sites, which was to meet on June 7, 1985 to make recommendations.¹¹²⁵ Dr. Perrault brought a motion for a consensus conference of all interested parties to fully discuss many of the issues arising from testing (which were not unique to the CRCS alone) such as notification of donors and other sociological, ethical, legal and medical issues. He, again, made it known that the CRCS would not delay testing for lack of alternative test sites, but rather, would delay notification of donors of their positive test results.¹¹²⁶ Dr. Leclerc-Chevalier's response to Dr. Perrault's suggestion of a consensus conference did not reflect the urgency of the situation. Dr. Leclerc-Chevalier promised that she would pass on the request to the CBC, but she could not ensure a positive response, and speculated that it might well have to go back to NAC AIDS for action. Dr. Clayton stated that NAC AIDS would not be able to fund such a conference. Nonetheless, the Committee members voted in favour of the motion, with one abstention.¹¹²⁷

638. The appreciation of the CRCS of the importance of early implementing of testing is evidenced by the fact that the Implementation Plan was submitted to NAC AIDS and the CBC prior to approval of the policy by its CRCS Board of Directors. The Board of Directors met on May 27 and 28, 1985 and approved the policy stated in CRCS Response to the Recommendations of the Task Force on AARV Testing, recognizing that the issues of reporting requirements, alternative test sites, and confidentiality had an impact on the CRCS but were within the domain of NAC AIDS.¹¹²⁸

¹¹²⁵ Evidence of Dr. Perrault, former National Director BTS, pp. 28767-28768.

¹¹²⁶ Evidence of Dr. Perrault, former National Director BTS, pp. 28729-28730; and

Ex. 635, CRC Vol. 32, Tab 22 (Memo to file from Dr. Perrault, dated May 21, 1985 re: May 15, 1985 NAC AIDS meeting).

¹¹²⁷ Ex. 635, CRC Vol., 32, Tab 22, (Memo to file from Dr. Perrault, dated May 21, 1985 re: May 15, 1985 NAC AIDS meeting).

¹¹²⁸ Ex. 81, Vol. 135, Tab 24, p. 103 (Memo from Dr. Perrault to the Commissioner, Ontario Division, dated August 6, 1985, enclosing Minutes of CRCS Board of Directors Meeting May 27-28, 1985).

6) Delay of Testing Caused by Delay of CBC Approval

639. The CRCS Implementation Plan for anti-HIV testing, which included a cost estimate, was received by the CBC on May 2, 1985.¹¹²⁹ Implicit in this plan was the contemplation of approval of testing by the CBC before June 30, 1985. The initiation of testing was set for August 1985 and full conversion was anticipated by early September.¹¹³⁰

640. A detailed budget was finalized on May 9, 1985.¹¹³¹ The CRCS sent the full testing budget proposal to the CBC on May 17, 1985, two days after NAC AIDS had approved the Implementation Plan. In its cover letter to Dr. Leclerc-Chevalier enclosing the supplementary budget submission, George Weber stressed the urgency surrounding this issue. The CRCS requested \$2.6 million to fund the testing program for 1985 and \$5.5 million for 1986.¹¹³²

641. Between the Executive Committee meeting of April 17, 1985 and the receipt of the CRCS budget, no process had been put in place by the CBC to expedite the approval of the forthcoming Implementation Plan or budget.¹¹³³ Between receipt of the testing budget and the meeting of the CBC on June 4 to 5, 1985 the Secretariat took no steps to evaluate the budget provided by the CRCS. Nor does it appear that the majority of the members of the CBC were presented with the CRCS plan or the budget by the Secretariat prior to their attendance at the June 4 to 5, 1985 meeting.¹¹³⁴

¹¹²⁹ Ex. 861, Vol. 193, Tab 1, p. 165 (Letter from Dr. Perrault to Dr. Clayton, dated May 1, 1985).

¹¹³⁰ Ibid, p. 169 (CRC BTS Introduction of Anti-LAV/HTLV III Screening).

¹¹³¹ Ex. 743, Tab 15 (Memo from Pat Humphreys to Dr. Davey, dated May 9, 1985).

¹¹³² Ex. 635, CRC Vol. 32, Tab 19 (Letter from George Weber to Dr. Leclerc-Chevalier, dated May 17, 1985 enclosing 1985 and 1986 Testing Budget Submissions).

¹¹³³ Evidence of Mr. Stephen Dreezer, Member of the CBC, p. 35912.

¹¹³⁴ Evidence of Mr. Ambrose Hearn pp. 35966-35967 and evidence of Dr. Leclerc-Chevalier when available.

642. Attached to the briefing material provided to all attendees by the CRCS was a position paper provided by the Secretariat. The position paper noted that testing of blood donations, if approved, could be implemented in mid-August,¹¹³⁶ however there was no recommendation to approve the CRCS Implementation Plan.¹¹³⁷

643. The CBC met on June 4 to 5, 1985. Despite the fact that the BMD had approved the Abbott test kit for use in Canada on May 28, 1985, the CRCS was not advised of this fact until June 11, 1985.¹¹³⁸

644. In order to underscore the importance of the testing issue at the CBC meeting, David Balfour, immediate Past President of the CRCS, attended along with Dr. Perrault, Dr. Derrick and Dr. Gilmore (the Chairman of NAC AIDS) to explain the technical, scientific and social aspects of the plan.¹¹³⁹ It was unusual for there to be any CRCS or NAC AIDS representatives at CBC meetings.

645. Following the presentations by Dr. Gilmore on behalf of NAC AIDS, and Drs. Perrault and Derrick on behalf of the CRCS, Mr. Dreezer asked whether it was appropriate to implement blood donation testing before alternative test sites were in place. The response he received was that testing should be implemented as soon as possible to allow the removal of potentially infected donations from the blood supply.¹¹⁴⁰

¹¹³⁶ Ex. 861, Vol. 193, Tab 1, p. 179 (Item 19 - Cost of testing blood and plasma donations for HTLVIII antibody, and costs of dealing with AIDS at the CRCS).

¹¹³⁷ *Ibid.*

¹¹³⁸ Ex. 635, CRC Vol. 32, Tab 33 (Letter from Dr. Liston to David Chin, dated May 28, 1985);
Ex. 1003, Vol. 249, Tab 29 (Letter from A.K. DasGupta to Dr. Derrick, dated June 11, 1985); and
Evidence of Dr. Davey, former Assistant National Director BTS, p. 28744.

¹¹³⁹ Ex. 720, p. 13 (Draft Record of Decisions, Meeting of the Canadian Blood Committee, June 4-5, 1985).

¹¹⁴⁰ *Ibid.*, p. 14.

646. After reports from the CRCS and NAC AIDS and a substantial number of questions by CBC members, the CBC commenced its deliberations about the CRCS budget, from which members of the CRCS and NAC AIDS were excluded. The minutes indicate that the CBC was prepared to provide only "approval in principle". The CRCS was to continue to "plan" for testing, subject to a review of the budget by the CBC Secretariat. Final approval would be given by June 30, 1985.¹¹⁴¹

647. The minutes are clear that not only did the CBC decline to approve the testing budget, it did not approve the program itself. The minutes clearly show that Mr. Hearn stated that the CRCS had enough money to deal with any cash flow problems, suggesting that there was sufficient money already to fund the program. He suggested that the CBC provide approval in principle that day, subject to members clearing the issue with their own governments, and giving the matter high priority at the provincial level.¹¹⁴²

648. The CBC did not instruct the CRCS to use funds in the fractionation account to implement testing¹¹⁴³ despite the fact that the CBC had previously used the fractionation account without consulting provincial treasury boards to ensure the survival of Connaught (when it could not sell product in Canada because of the BoB requirements for heat-treatment).¹¹⁴⁴

MR. DREEZER:...Connaught -- the Ministers of Health had previously agreed that there should be a set number of fractionation plants in Canada, that Connaught would be one of them. That this should continue, the Bureau of Biologics had said that you had to switch from non-heat-treated to heat-treated Factor VIII.

¹¹⁴¹ *Ibid*, p. 18, paragraph 93.

¹¹⁴² *Ibid*, p. 18, paragraph 89.

¹¹⁴³ *Evidence of Mr. Claude Morin, former National Administrator*, p. 39900.

¹¹⁴⁴ *Evidence of Mr. Dreezer, Member of the CBC*, pp. 35928-35929; and

Ex. 860, Vol. 192, Tab 10, p. 244 (Record of the Decision of the Canadian Blood Committee, dated April 17, 1985).

The policy decisions if you like were all in place. The Canadian Blood Committee knew exactly the scope, the boundaries of what was expected of it with regard to Connaught.

Connaught came to the CBC and said, "As a matter of urgency, because of the changeover to heat-treatment we need some cash flow assistance to keep us in business. If we don't then we are going to have start breaking up our teams" ...

And Connaught was making the point, "Look, if you don't give us some money to help us through this period, we are going to have to break up our teams, and you can kiss your Canadian fractionation capability goodbye."

And that was the context for that decision...

MS. EDWARDH: Yes. And I appreciate that, Mr. Dreezer, but surely what the Red Cross had said, and was saying, and that NACAIDS said, and that the task force said, and anyone else who was dealing with the issue said, was that there are asymptomatic donors who look well, but are infected and infectious who are perspective blood donors and there is a substantial risk they will transmit AIDS. And there is a risk and some urgency as well.

MR. DREEZER: Okay. The big difference is that in that case nobody was saying to us you have to make an instantaneous decision. There were other issues that were being discussed at the same time, such as...alternate test sites.

And from our point of view, as long as we knew other organizations that had a responsibility in the whole area of AIDS were looking at these issues and we were being presented with a budget to review as well, it was a totally different situation from the Connaught one. Plus, at this point in time, we had not received any policy direction, if you like from the Ministers, with regard to this particular issue.

We hadn't, because it was a significant budget item, and none of us would have made provision for it in our budgets, we had the extra concern of whether in fact we had enough discretionary money to deal with this, or if there was no discretionary money whether we had to go through some other process, and that would vary from province to province across the country.

MS. EDWARDH: But that is true for Connaught. I mean, Connaught was a million dollar ticket. This is a little more, but no one had made a provision for it in their budget.

MR. DREEZER: But the decision had already been taken. The Ministers had made it very clear with Connaught that Connaught will continue...That was continuation of something existing, this was something -- the add-on of something brand new.¹¹⁴⁵

649. The CRCS had anticipated approval of the program soon after the June CBC meeting. The date set for full conversion of the Canadian blood supply was September 9, 1985.

In anticipation of that approval, Dr. Davey drafted a memo dated June 3, 1985, which provided information to Medical Directors and Technical Supervisors about the steps which would need to be taken. The memo requested information from each centre about its staffing and equipment requirements, indicated that staff would have to be hired and supplies ordered, a testing procedural manual would have to be prepared, and staff would have to be trained. The only blank left to be filled in on this memo was the date of CBC testing approval. Because approval was not provided, this memo was not sent.¹¹⁴⁶

650. The CRCS was not advised of the CBC's decision to give "approval in principle" only until Dr. Leclerc-Chevalier wrote to George Weber on June 10, 1985.¹¹⁴⁷ This letter stated that the CRCS was to continue "to plan" while the CBC Secretariat assessed the budget and committee members consulted with their provincial ministries. The CRCS had no further planning to do. What was needed was approval to make the commitments and expenditures that its plan required. Dr. Leclerc-Chevalier wrote that,

...[t]he Committee is not in a position to approve donation testing until federal and provincial health ministries have an opportunity to discuss issues such as alternative test sites, testing for diagnostic purposes, information to donors...

Dr. Leclerc-Chevalier promised that the CBC would advise the CRCS by June 30, 1985 of the status of approval of its Implementation Plan. The delay in CBC approval pushed back the conversion date of the Canadian blood supply to the end of September 1985.

651. On the same day, Dr. Leclerc-Chevalier wrote to Dr. Perrault regarding the relocation of NRL and a proposal to rent the facilities at the Gage Institute to be used to test blood and plasma donations. At the end of the letter, she reminded Dr. Perrault that with respect to testing, "it is understood that, at the present time, no additional resources have been

¹¹⁴⁶ Ex. 635, CRC Vol. 32, Tab 38 (*Memo from Dr. Davey to all Centres, date re=Anti-HTLV III Testing of Blood Donors, June 3, 1985*); and

Evidence of Dr. Davey, former Assistant National Director BTS, p. 28757.

¹¹⁴⁷ Ex. 746, Tab 13 (*Letter from Dr. Leclerc-Chevalier to George Weber, dated June 10, 1985*).

approved by the CBC.¹¹⁴⁸ This confirmed that the CRCS had no authority to expend the funds or make the commitments necessary to implement testing, especially given its past experience with the CBC.¹¹⁴⁹

652. On June 20, 1985, Dr. Leclerc-Chevalier wrote to George Weber advising that the CBC required until July 5th to respond to the CRCS budgetary request for testing.¹¹⁵⁰ A federal/provincial conference to discuss many of the sociological, ethical, legal and medical issues surrounding AIDS and testing had been requested by the federal government and was delayed from June 28, 1985 to July 4, 1985. Dr. Leclerc-Chevalier promised that the CBC would advise the CRCS of the status of its proposal by July 5, 1985. This delay pushed the full conversion date back once again. Accordingly, the CRCS ensured that NAC AIDS was involved in the implementation process from the outset.¹¹⁵¹

653. On June 24, 1985 the Secretariat of the CBC met to discuss two options regarding the approval of testing blood donations. The first option was to obtain agreement from members on the testing of blood donations before the July 4 meeting. This could be done on the basis that the CRCS budget was reviewed, found to be acceptable, and that the other related issues raised at the time of discussions on testing would be considered at the July 4th meeting. The second option was to wait until after the July 4 meeting, inform members of the decisions made and to obtain their agreement. The majority of the Secretariat felt that the second option was more in line with the discussion at the June 4 and 5, 1985 meeting.¹¹⁵²

¹¹⁴⁸ Ex. 876, Vol. 208, Tab 56, pp. 26943-26944 (*Letter from Dr. Leclerc-Chevalier to Dr. Perrault, dated June 10, 1985*).

¹¹⁴⁹ *Evidence of Dr. Perrault, former National Director BTS, p. 28787.*

¹¹⁵⁰ Ex. 746, Tab 14 (*Letter from Dr. Leclerc-Chevalier to George Weber, dated June 20, 1985*).

¹¹⁵¹ Ex. 648, Vol. 148, Tab D18 (*Minutes of NACAIDS meeting, dated October 9, 1984*);

Ex. 627, CRC Vol. 24, Tab 35 (Memo from Dr. Derrick to Dr. Perrault, dated August 2, 1984).

¹¹⁵² Ex. 877, Vol. 209, Tab 9, (*Memo to File by Dr. D. Leclerc-Chevalier, dated June 24, 1985*).

654. The final review of the supplementary testing budget did not occur until June 26, 1985 when Mr. Randall Klotz met with senior staff of the CRCS to review the budget submission.¹¹⁵³ The amount approved by the Secretariat was within 3% of what the CRCS requested.¹¹⁵⁴ Mr. Morin testified before the Inquiry that it was completely unnecessary for the CBC to review this submission in this amount of detail.¹¹⁵⁵ Mr. Morin indicated, nevertheless, that a full review of the supplementary budget could have been completed in one or two weeks.¹¹⁵⁶

655. The CRCS was disappointed and frustrated by the CBC delays. Dr. Perrault had urged a consensus meeting of health authorities to address the difficult questions of uniform reporting requirements, notification of donors, information to donors, and alternative test sites. However, it continued to be the position of the CRCS that it would not delay *testing* until alternative test sites were up and running, but rather, it would delay *notification* of donors. Nor would the CRCS delay testing until the other issues were determined.¹¹⁵⁷ The mandate of the Federal/Provincial Conference on AIDS was to share information, to reach a consensus on matters requiring immediate action, and to determine who was responsible for taking action.¹¹⁵⁸

¹¹⁵³ Ex. 877, Vol. 209, Tab 12 (*1985 Supplementary Budget for additional resource requirements for the Canadian Red Cross Society to deal with the AIDS problem*).

¹¹⁵⁴ *Ibid* at p. 26046; and

Ex. 883, Vol. 215, Tab 3, p. 27301 (*Summary of 1985 (6 months) Proposed Budget for Introducing Anti-HTLV-III Screening (Revised June 26, 1985)*).

¹¹⁵⁵ *Evidence of Mr. Morin, former National Administrator*, p. 39788.

¹¹⁵⁶ *Evidence of Mr. Morin, former National Administrator*, p. 39790.

¹¹⁵⁷ Ex. 720 (*Draft Record of Decisions, Meeting of the Canadian Blood Committee, dated June 4 - 5, 1985, paragraph 75*);

Evidence of Dr. Perrault, former National Director BTS, pp. 28762-28763; and

Ex. 635, CRC Vol. 32, Tab 22 (*Memo from Dr. Perrault to file dated May 21, 1985 re: May 15 NAC AIDS meeting*).

¹¹⁵⁸ Ex. 636, CRC Vol. 33, Tab 27 (*Minutes of Federal-Provincial AIDS Conference, dated July 4, 1985*).

The CRCS saw no reason for the CBC to delay approval of the entire CRCS testing program until after this meeting.¹¹⁵⁹

656. On July 4, 1985 Dr. Davey reported at the conference that the CRCS had been asked by the CBC to place its testing program "on hold" until its request for resources had been examined in detail and the program was funded.¹¹⁶⁰ He commented that the agreements and recommendations generated at the meeting of the Task Force on AARV Testing contemplated that testing by the CRCS begin as soon as possible within 10 to 12 weeks of approval, but that notification of test results would be delayed until alternative test sites were operational. NAC AIDS presented its report, which stressed the need for provincial alternative test sites to be up and running at the same time as the CRCS commenced testing. It became clear at that meeting that few provinces had taken any steps to address the issue of alternative test sites or reporting requirements, despite the fact that the issue had originally been raised four months earlier at the March meeting of the Task Force on AARV Testing. The frustration felt by the CRCS at the slow moving response by the public health authorities was echoed by many of the participants at the meeting, who felt that they were too low on the bureaucratic ladder to make decisions. The persons who attended the meeting:

...were involved intimately with AIDS in their provincial jurisdictions and were aware of what was happening. However, many decisions have to be made, at a provincial level much higher than that of the present participants. It was considered that the results of the meeting might have been more productive or might have led to more decision making if it had been conducted with Deputy Minister or Assistant Deputy Ministers present...

...Many participants felt that the upper levels of health departments did not really realize the important significance of AIDS and the future developments likely to occur. As far as AIDS in Canada is concerned, no forum exists where information exchange can take place among provinces, and further ad hoc meetings of this type were needed.¹¹⁶¹

¹¹⁵⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28729-28730.

¹¹⁶⁰ Ex. 636, CRC Vol. 33, Tab 27, p. 8 (Minutes of Federal-Provincial AIDS Conference, dated July 4, 1985 at p. 36525).

¹¹⁶¹ Ex. 636, CRC Vol. 33, Tab 27, p. 32 (Minutes of Federal-Provincial AIDS Conference, dated July 4, 1985).

657. Dr. Davey testified that, in general, the participants at the meeting were provincial epidemiologists with no decision-making authority. In his view, their presence demonstrated the lack of urgency and attention being given to this issue by the provinces. The minutes of this meeting indicate that approval from the CBC was expected on July 12, 1985.¹¹⁶²

658. Dr. Davey informed all BTS Centres of this expected new approval date by way of a telex dated July 5, 1985.¹¹⁶³

659. On July 9, 1985, the CRCS was forced to postpone its training session for technical supervisors, which had been planned since late April, as it was impossible, without program approval, to continue to reserve the facilities, equipment, and accommodations and proceed with training its technical supervisors without the equipment and the assistance of Abbott staff. Because of the postponement of approval the CRCS was unable to contract with Abbott.¹¹⁶⁴

660. The CRCS expected that it would receive program approval on July 12, 1985, as had been promised at the July 4 Federal/Provincial Conference on AIDS. To that end, Dr. Davey revised his June 3, 1985 memo providing information to Centres as to how implementation would proceed. He also enclosed a questionnaire requesting that Centres list their equipment and staffing needs for testing. Once again, the date of CBC approval was left blank. The memo was not sent as July 12, 1985 came and went without a word from the CBC regarding approval of the CRCS Implementation Plan.¹¹⁶⁵

¹¹⁶² Ex. 636, CRC Vol. 33, Tab 27, p. 36522 (*Summary of Agreements and Recommendations from Federal-Provincial Meeting on AIDS, dated July 4, 1985*).

¹¹⁶³ Ex. 636, CRC Vol. 33, Tab 32 (*Telex from Dr. Davey to BTS Centres Administrators re: Anti-LAV/HTLV Screening: Federal/Provincial Conference of July 4, 1985, dated July 5, 1985*).

¹¹⁶⁴ Ex. 637, CRC Vol. 34, Tab 4 (*Memo from Pat Humphreys to Medical Directors, dated July 9, 1985*); and *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28811-28819*.

¹¹⁶⁵ Ex. 743, Tab 16 (*Memo from Dr. Davey to Medical Directors and Technical Supervisors, dated June 12, 1985*).

661. On July 15, 1985, Dr. Derrick took the initiative and phoned Mr. Klotz to inquire as to whether all the provinces had given approval for the CRCS to commence AIDS testing. Mr. Klotz explained that a number of provinces had been contacted and when the rest of them had been reached, the Secretariat would contact Mr. Hearn to inform him of results and issues. Dr. Derrick expressed his concern on timing and the growing pressure upon the CRCS from users and the press. Mr. Klotz noted in a memo to file following this conversation that he did not inform Dr. Derrick of a number of developments with respect to Ontario, primarily, because management board approval of the testing program would take 2 to 3 weeks and that Ontario would prefer to delay the CRCS testing to allow AIDS diagnostic sites to be ready in the province.¹¹⁶⁶

662. Dr. Derrick explained that George Weber was ready to telex Ambrose Hearn on this subject if the Secretariat did not have "good news" that day. It was agreed to defer this approach until the Secretariat contacted Mr. Hearn the next day with information as to each province's support for the requested resources for 1985.¹¹⁶⁷

663. On July 16, 1985 Dr. Davey, Dr. Naylor, Dr. Walker, and Dr. Derrick met with Mr. Klotz. Dr. Derrick expressed concern about the delays in providing the CRCS with approval to undertake testing. Dr. Davey reiterated that the time between approval for the testing and full conversion was estimated at 10 to 12 weeks.¹¹⁶⁸

664. On July 18, 1985, Dr. Davey received a telephone call from Mr. Hearn informing him that as of mid-July, the only province which was holding out on approval of the budget was Ontario.¹¹⁶⁹ Ontario's approval was expected within two weeks. Dr. Davey was told that no media statement was to be made indicating that Ontario was the province whose approval was still outstanding. Mr. Hearn reiterated that the CRCS was not to commit to any new national

¹¹⁶⁶ Ex. 877, Vol. 209, Tab 21 (*Memo to File by Randy Klotz, July 15, 1985*).

¹¹⁶⁷ *Ibid.*

¹¹⁶⁸ Ex. 877, Vol. 209, Tab 22 (*Note to File by Randy Klotz, July 16, 1985*).

¹¹⁶⁹ *Evidence of Dr. Gilmore, former member of NAC AIDS, p. 25319.*

expenditures.¹¹⁷⁰ The new expected date for approval was August 1, 1985. Full implementation of testing across the country was now no longer possible until the end of October.

665. The CRCS had no confidence that the August 1st deadline would be met. Previous deadlines had been broken. Funding approval by the CBC was notoriously late. Dr. Davey testified that the CRCS had no idea when approval would be granted since the CBC had granted "approval in principle" only and was specifically given instructions not to proceed with the program¹¹⁷¹:

Well, I don't see how I could conceivably do that when I have been given explicit instructions not to by the chairman, of what amounts to the governing body in this --...

...-- and as far as confidence in that 1st August date, I mean our expected dates of approval had been June the 4th, June the 30th, July the 4th and July the 12th. They had all failed. So why should I have anymore confidence at this time in a 1st August promise.

I mean this was a very frustrating, and unwelcome communication, six days after the last deadline had expired.¹¹⁷²

666. The CRCS could not commit to any expenditure while there was "approval in principle" only. The CBC had not only withheld approval of the budget; it had withheld approval of the entire program as was stated in a Briefing Note to the Minister dated June 14, 1985.¹¹⁷³ It was clear that the CRCS could continue to "plan", but was not permitted to commit any funds.¹¹⁷⁴ Had it done so at a time when there were clearly no funds allocated to

¹¹⁷⁰ Ex. 660A, CRC Vol. 58, Tab 10 (*Memo from Dr. Davey to Dr. Perrault, dated July 18, 1985 re: screening for HTLV-III Antibodies*).

¹¹⁷¹ *Evidence of Dr. Perrault, former National Director BTS, pp. 28785-28789.*

¹¹⁷² *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28821-28822.*

¹¹⁷³ Ex. 636, CRC Vol. 33, Tab 11 (*Briefing Note for the Minister on Factor VIII and Testing of Blood Donations, dated June 14, 1985*).

¹¹⁷⁴ *Evidence of George Weber, former Secretary General, pp. 40291-40281, 40748-40750.*

this program by the CBC, the CRCS would have put itself at risk for covering the entire \$2.5 million expenditure required in 1985. Such an expenditure, without approval by the CBC, could have bankrupted the CRCS within a year.¹¹⁷⁵

667. While "approval in principle" was something which the CRCS had never before encountered, the CRCS understood that it was not to commit to a large ongoing operational cost without CBC authorization.¹¹⁷⁶ The funds in the fractionation account was a CRCS liability not an asset. It was held for the CBC in trust.¹¹⁷⁷ This was not simply a matter of the CRCS writing a cheque. The CBC had previously expressed extreme displeasure when the CRCS spent money without prior approval. It was previously made very clear that a repeat of "VAXination" was not to happen. Otherwise, CRCS funding might be jeopardized.¹¹⁷⁸

668. There was nothing more that the CRCS could have done to prepare the CBC for the cost of testing earlier. It had alerted the CBC to the program and its potential cost in the fall of 1984. Contingency budgets were not considered by the CBC. Mr. Dreezer testified that the CBC would not have approved a \$2 million allocation for testing in a contingency budget.¹¹⁷⁹ There was little information about what would be required when the CRCS originally submitted its 1985 budget in August of 1984. While the CBC Secretariat advised the CRCS to deal with this in a supplementary budget,¹¹⁸⁰ the CBC made it known that

¹¹⁷⁵ *Evidence of Claude Morin, former National Administrator, pp. 39782-39783.*

¹¹⁷⁶ *Evidence of Dr. Perrault, former National Director BTS, pp. 28785-28789.*

¹¹⁷⁷ *Evidence of Claude Morin, former National Administrator, p. 39900;*

Evidence of George Weber, former Secretary General, pp. 40815-40816; and

Evidence of Dr. Perrault, former National Director BTS, pp. 28785-28789, 29981-29985.

¹¹⁷⁸ *Evidence of Chris Patterson, former Board of Directors member, pp. 40204-40209.*

See discussion in Volume I - CBC for a full discussion of Vax.

¹¹⁷⁹ *Evidence of Stephen Dreezer, member of the CBC, p. 35885.*

¹¹⁸⁰ *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28578-28585.*

supplementary budgets were discouraged. However, this was obviously a necessary expenditure.¹¹⁸¹ The CRCS advised the CBC in its 1985 budget submission that a supplementary budget would be forthcoming. In the fall of 1984, the CRCS had given the CBC a ballpark figure as an estimate as to how much testing would cost.¹¹⁸²

669. On August 1, 1985, the CBC approved the CRCS budget proposal and program for anti-HIV testing. The CBC made it clear that approval was granted only for the 1985 year and that a new budget proposal would have to be submitted for the 1986 year, using the experience gained from testing in 1985.¹¹⁸³ On August 12, 1985, Dr. Davey advised Medical Directors of the CBC decision and wrote, "We are sorry, but not responsible, for the delay..."¹¹⁸⁴ The CBC delays meant that full conversion of the blood supply could not be done prior to November 1, 1985.

670. Besides Randy Klotz's memo to file dated July 15, 1985, there is no documentary evidence showing that the CRCS complained about each CBC delay, despite its frustration. Dr. Davey testified that this is because approval appeared to be imminent week after week after week. There was no week for almost a month that approval was not imminent.¹¹⁸⁵ The CRCS had done all it could to stress the urgency of the situation to the CBC. It had made this clear in its cover letter enclosing the budget submission and it had asked for Dr. Gilmore to accompany Dr. Perrault to the CBC meeting. In the words of Dr. Pope:

¹¹⁸¹ Evidence of Claude Morin, former National Administrator, pp. 39767-39768.

¹¹⁸² Evidence of Chris Patterson, former Board of Directors member, pp. 40323-40324;

Evidence of Dr. Perrault, former National Director BTS, pp. 30415-30417; and

Ex. 634, CRC Vol. 31, Tab 11 (Memo from Dr. Perrault to Secretary General, dated April 12, 1985 re: August 1985 budget and Preparations for 1985 budget).

¹¹⁸³ Ex. 637, CRC Vol. 34, Tab 21 (Letter from Elaine Boily to George Weber, dated August 1, 1985 confirming budget approval).

¹¹⁸⁴ Ex. 637, CRC Vol. 34, Tab 27 (Memo from Dr. Davey to Medical Directors, dated August 12, 1985 re: testing approval).

¹¹⁸⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 28860-28862.

There is one feature about a delay like this [re: licensing the CRCS]. At the beginning of the delay you don't know you are going to have one.¹¹⁸⁶

671. The lack of confidence by the CRCS in the CBC approval date is indicated by the fact that a third revision to the June 3 memo to Medical Directors and technical staff finally went out on July 19, 1985 and provided all relevant information to Centres but did not mention any date for CBC program approval.¹¹⁸⁷

672. George Weber explained that the CRCS did not vocally express its frustration to the CBC because of the negative reaction which would have resulted.¹¹⁸⁸ The CRCS had to manage the blood program and could not do so effectively without maintaining cordial relations with its funder. The CBC and Ministers of Health reacted very negatively to what they described as CRCS "antics".¹¹⁸⁹ The CBC was formed, in part, to put an end to this. The CBC "nickel and dimed" the CRCS to the detriment of the blood program when the CRCS did not bend to its will.¹¹⁹⁰ That the CBC, and Ontario, the largest provincial funder for testing, were very sensitive to criticism is evidenced by the reaction to the *Globe and Mail* article of April 15, 1985 and warnings to CRCS not to identify Ontario as the hold-out province.¹¹⁹¹

¹¹⁸⁶ Evidence of Dr. Pope, former Assistant Director, LCDC, p. 42810.

¹¹⁸⁷ Ex. 637, CRC Vol. 34, Tab 11 (Memo from Dr. Davey to Technical Supervisors and Medical Directors, dated July 19, 1985).

¹¹⁸⁸ Evidence of George Weber, former Secretary General, pp. 40797-40801.

¹¹⁸⁹ See discussion of CBC in Part I of these submissions.

¹¹⁹⁰ Ex. 737, Tab 15 (Memo to file by George Weber, dated November 3, 1988); and

Evidence of Dr. Perrault, former National Director BTS, p. 30721.

¹¹⁹¹ Ex. 860, Vol. 192, Tab 10, p. 249 (Record of Decisions of the Executive Committee of CBC, dated April 17, 1985); and

Ex. 660A, CRC Vol. 58, Tab 10 (Memo from Dr. Davey to Dr. Perrault, dated July 18, 1985 re: screening for HTLV-III Antibodies).

673. The CRCS met its projected time frame.¹¹⁹² The 10-to-12 week conversion period provided for in the Implementation Plan was achieved.¹¹⁹³ Testing commenced in some centres in the last week of September, all centres had begun testing by October 11, 1985¹¹⁹⁴ and all inventory in hospitals was fully converted by November 4, 1985. Centres were encouraged to achieve full conversion even earlier if possible.¹¹⁹⁵

- **Vancouver** - October 7, 1985.¹¹⁹⁶
- **Calgary, Edmonton** - September 19, 1985.¹¹⁹⁷
- **Ottawa** - October 2, 1985.¹¹⁹⁸
- **Montreal, Quebec** - October 10, 1985.¹¹⁹⁹
- **Hamilton** - September 1985.¹²⁰⁰

¹¹⁹² There was no evidence before the Commission of Inquiry as to when each and every centre began testing. There was no such evidence for the following centres: Regina; Sudbury; St. John's; and Charlottetown.

¹¹⁹³ Ex. 746, Tab 19 (Memo from Dr. Davey to all Medical Directors, dated October 16, 1985).

¹¹⁹⁴ Ex. 746, Tab 18 (Minutes of Ad Hoc AIDS Implementation Working Group Meeting, dated October 15, 1985).

¹¹⁹⁵ Ex. 746, Tab 19 (Memo from Dr. Davey to Medical Directors, dated October 16, 1985).

¹¹⁹⁶ Evidence of Dr. Rekart, Director of STD Clinic, B.C. Ministry of Health, pp. 5227-5229; and
Evidence of Dr. Buskard, former Vancouver Centre Medical Director, pp. 5783-5784

¹¹⁹⁷ Evidence of Dr. Waters, Director, Communicable Disease Control and Epidemiology, Alberta Health, pp. 6176-6177;

Evidence of Dr. Larke, Deputy Medical Director, Edmonton Centre, pp. 6784-6785; and

Ex. 147, Vol. 61, Tab 13 (Memo from Dr. Hannon to hospitals, dated October 9, 1985).

¹¹⁹⁸ Ex. 603, Vol. 154, p. 118 (Letter from Dr. Rock to Dr. Carlier, dated November 1, 1985); and
Evidence of Dr. Rock, former Ottawa Centre Medical Director, p. 24151.

¹¹⁹⁹ Ex. 379, Vol. 106, Part I, Tab 3, p. 00003 (Memo from Dr. Guevin to Dr. Davey, dated October 10, 1985).

¹²⁰⁰ Evidence of Dr. Blajchman, Hamilton Centre Medical Director, pp. 19538.

- **Saskatoon** - September 26, 1985.¹²⁰¹
- **Regina** - Dr. Alport testified that testing began in Regina towards mid- to end of September, 1985.¹²⁰²
- **Winnipeg** - September 23-25, 1985 and was completely converted by October 1, 1985.¹²⁰³
- **Toronto** - September 27, 1985.¹²⁰⁴
- **London** - September 20-29, 1985.
- **St. John's** - October 1985.¹²⁰⁵
- **Saint John** - October 1, 1985.¹²⁰⁶
- **Halifax/P.E.I.** - October 1985.¹²⁰⁷

674. On August 27, 1985, Dr. Derrick wrote to Dr. Liston thanking the HPB for arranging the July 4, 1985 Federal/Provincial Conference on AIDS and for stressing the message about the need for alternative test sites. He noted that there were loose ends yet to be tied up before the CRCS began testing. The CRCS could only notify donors in provinces where there were alternative test sites. Otherwise, the CRCS would be delaying notification. He requested a follow-up conference to deal with other outstanding issues.¹²⁰⁸

¹²⁰¹ Evidence of Dr. McSheffrey, *Saskatoon Centre Medical Director*, p. 8677.

¹²⁰² Evidence of Dr. Alport, *Regina Centre Medical Director*, p. 8849.

¹²⁰³ Evidence of Dr. Schroeder, *Winnipeg Centre Medical Director*, pp. 9873-9876.

¹²⁰⁴ Evidence of Dr. Pinkerton, *Director, Sunnybrook Hospital Blood Bank*, p. 3829.

¹²⁰⁵ Ex. 338, Vol. 98, Tab A, p. 42 ("AIDS Testing Now Underway In Province" in *Evening Telegram*, dated November 28, 1985).

¹²⁰⁶ Evidence of Dr. MacKay, *Saint John Centre Medical Director*, pp. 11839-11840.

¹²⁰⁷ Evidence of Dr. Sullivan, *Administrator, Community Health Services, Nova Scotia Department of Health*, p. 12742.

¹²⁰⁸ Ex. 1004, Vol. 250, Tab 37 (Letter from Dr. Derrick to Dr. Liston, dated August 27, 1985).

675. Dr. Liston did not take up the issue of a second consensus conference. Dr. Derrick reported to George Weber by way of a memo dated October 10, 1985 that the issue of reporting requirements across the country was becoming increasingly complex. It appeared that the CRCS would get no assistance from NAC AIDS, but rather, it was going to have to negotiate with each province individually to try to obtain uniform reporting requirements across the country.¹²⁰⁹

676. In part, as a result of the efforts by the CRCS, all provinces had alternative test sites operational by the end of October, except for Alberta, which started testing on December 1, 1985.¹²¹⁰ Quebec established such sites in March 1986.¹²¹¹ The CRCS insistence on the development of alternative test sites by the provinces at the same time as the CRCS began testing was not misguided. Alternative testing sites were crucial to avoid the "magnet effect"¹²¹². Indeed, the "magnet effect" was experienced at some Centres, such as Ottawa and Montreal¹²¹³, anyway. This may have been due to the fact that the CRCS was trusted more by donors to maintain confidentiality.¹²¹⁴ Or it may have been due to insufficient publicity about alternative test sites in Montreal, which meant that donors were using the Montreal blood donor clinics as diagnostic test sites. Consequently, Dr. Decary testified that she launched a

¹²⁰⁹ Ex. 639, CRC Vol. 36, Tab 15 (Memo from Dr. Derrick to George Weber, dated October 10, 1985); and
Ex. 639, CRC Vol. 36, Tab 13 (Minutes of the NAC AIDS Meeting of October 9, 1985).

¹²¹⁰ Evidence of Dr. Waters, Director, Communicable Disease Control and Epidemiology, Alberta Health, pp. 6123-6124; and
Evidence of Dr. Davey, former Assistant National Director BTS, and Evidence of Dr. Perrault, former National Director BTS, pp. 28850-28852

¹²¹¹ Evidence of Dr. Hebert, Deputy Medical Director of Quebec City, pp. 15119-15120.

¹²¹² Evidence of Dr. Klein, physician in private group practice, pp. 2819-2822;
Evidence of Dr. Johnstone, former Director of Division of Epidemiology, Ministry of Health, B.C., p. 4358; and

Evidence of Dr. Rekart, Director of STD Clinic, B.C. Ministry of Health, pp. 5239-5240.

¹²¹³ Evidence of Dr. Remis, Montreal Epidemiologist, pp. 41230, 41242-41244.

¹²¹⁴ Evidence of Dr. Berger, physician in private group practice, p. 17966.

publicity campaign and contacted the Corporation of Physicians to discourage it.¹²¹⁵ Dr. McSheffrey testified that at least one Saskatoon donor used the CRCS for testing in 1986.¹²¹⁶ Dr. Alport testified that people would occasionally phone in at his Centre to ask for their test results.¹²¹⁷ There was also some evidence that some physicians were sending their patients for testing at the CRCS, rather than alternative test sites. The CRCS immediately reacted to rectify this when such a situation came to its attention.¹²¹⁸

677. Once the wheels were in motion to implement testing, the CRCS attempted to negotiate with each provincial health authority to ensure consistent reporting requirements across the country. Of particular concern was the position taken in Nova Scotia that initially reactive ELISA test results would be reportable.¹²¹⁹ It was only with considerable difficulty that the CRCS ensured that only confirmed Western Blot positive test results would be reportable.

678. These negotiations required that Drs. Perrault and Derrick expend considerable time and resources contacting the public health authorities in every province. All provinces had

¹²¹⁵ *Evidence of Dr. Decary, Montreal Centre Medical Director, pp. 16124-16125.*

¹²¹⁶ *Evidence of Dr. McSheffrey, Saskatoon Centre Medical Centre, pp. 8947-8949.*

¹²¹⁷ *Evidence of Dr. Alport, Regina Medical Director, p. 8949.*

¹²¹⁸ *Evidence of Dr. Waters, Director, Communicable Disease Control and Epidemiology, Alberta Health, p. 6499;*

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, and evidence of Dr. Alport, Regina Centre Medical Directors, pp. 8950-8951;

Evidence of Roy West, former Provincial Epidemiologist, Saskatchewan Health, pp. 9371-9372; and

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9884-9885.

¹²¹⁹ *Evidence of Dr. Sullivan, Administrator, Community Health Services, Nova Scotia Department of Health, pp. 12448-12456; and*

Ex. 293, Vol. 88, pp. 34-35 (Certified true copy of an Order of His Honour the Lieutenant Governor of Nova Scotia made October 16, 1985 signed by H.F.G. Stevens, Q.C. with Attachment of Schedule A).

different legislation and reporting requirements and did not seem to be motivated to standardize their requirements.¹²²⁰

679. This is an example of the hurdles facing the CRCS in operating a national blood system in a federal system where health including public health is a provincial responsibility with no national body exerting leadership.

680. The implementation date of full anti-HIV testing in Canada must be considered in its proper perspective. The entire Canadian blood supply was fully converted by November 4, 1985, and virtually all blood donated after October 11, 1985 was tested.¹²²¹ Comparisons with implementation dates of other countries must be made on this basis. Even with the delays caused by the CBC, Canada still ranked well as compared with other countries.¹²²²

681. Testing commenced in Canada at about the same time as many other developed countries, and before some others. For example, Denmark started testing on January 1, 1986, Ireland in October 1985, Israel in April 1986 and South Africa from August to November, 1985. The CRCS implemented testing about the same time as Germany, the U.K., Switzerland and Finland. Although the U.S. implementation date is often cited as March 1985, this is when the program began, not when the Americans achieved full conversion. Most blood banks in the United States were not testing until mid-summer of 1985. Most American blood Centres did not

¹²²⁰ Ex. 640, CRC Vol. 37, Tab 13 (*Summary of the proceedings of a meeting of the CRC BTS Centre Medical Directors held on November 6, 1985*);

Ex. 642, CRC Vol. 39, Tab 40 (*Summary of proceedings of a meeting at the Ontario Ministry of Health, dated February 6, 1986*);

Ex. 642, CRC Vol. 39, Tab 41 (*Minutes of summary of proceedings of the meeting of Ontario Medical Directors on February 6, 1986*); and

Ex. 641, CRC Vol. 38, Tab 20 (*Report on Federal Provincial Ad Hoc Meeting on AIDS, dated December 9, 1985*).

¹²²¹ Ex. 746, Tab 18 (*Minutes of Ad Hoc AIDS Implementation Working Group Meeting, dated October 15, 1985*).

¹²²² Ex. 715, Vol. 155, Tabs 23, 32, 33, 34 and 35 (*International Overview of Donor Screening Measures Introduced in 1983*).

test inventory, but merely tested newly drawn blood.¹²²³ The United States had no funding problems, nor did they need approval - blood banks simply incurred their own charges and blood was paid for on a cost recovery basis. The CRCS November 1, 1985 date was the date that all incoming donations, as well as inventory, were tested:

Certainly, some testing by some blood centres began in the time frame that you've mentioned. As was described I believe by other witnesses, the blood system in the United States is a very complex one and quite unlike that in Canada. It's a variety of centres, principal amongst them is the American Red Cross, but also a combination of hospital, community-based centres, private enterprises, et cetera.

It would be impossible for any organization, even one centrally organized, to have everything in place overnight. There is certainly no evidence that the Americans all began testing the second day after the test became available.

As a matter of fact, I've seen other documentation that in some states it wasn't until June that it was mandated that HIV testing come underway.

The comparative studies with Canada hint that nothing was done until November 1985. That is the actual date when absolutely every centre in Canada had every unit of blood in-house tested and all inventory stock tested. That is the final date.¹²²⁴

1223

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22463-22466, 22861.

NOTE: There is no evidence on the record as to whether untested inventory was utilized or discarded.

1224

Evidence of Dr. Larke, Edmonton Centre Deputy Medical Director, pp. 6784-6785.

E.

CRC'S RELATIONSHIP WITH HEMOPHILIACS AND HEMOPHILIA TREATERS

1) Role of the CRCS in the Treatment of Hemophiliacs

682. The CRCS does not play a clinical role in the treatment of patients. The role of the CRCS and the Medical Directors of each local centre, was to supply the blood components and derivatives requested by hospitals and treating physicians. It also provided information to physicians, hospitals, hemophilia specialists and others who administered blood components or derivatives as part of a medical regimen¹²²⁵ both verbally, when requested, and through its booklet, the *Clinical Guide to Transfusion*, which was distributed by the CRCS to all medical staff at hospitals.¹²²⁶ The respective responsibilities of treating physicians and of the CRCS were set out in the 1980 *Clinical Guide to Transfusion* as follows:

1. Canadian Red Cross Responsibilities

- to supply through regional blood transfusion centres, blood and blood products to meet the requirements of all the hospitals served by those centres
- to establish standards for selection of donors to ensure both the safety of the donor at the time of blood collection and the quality of the products obtained from the donation
- to test each donation for major blood groups, significant antibodies, and certain diseases transmissible by transfusion
- to ensure through proper preparation, storage and quality control surveillance, the quality of each product prepared and issued
- to maintain records to ensure all products are traceable
- to act as a resource in matters relating to transfusion

2. Physician Responsibilities

- to evaluate the precise clinical need
- to determine appropriate products for each specific patient and the quantity and rate of administration
- to indicate the urgency of the transfusion requirement
- to provide adequate clinical information to the hospital blood bank
- to notify the blood bank promptly if crossmatched blood is no longer necessary, so it may be reclaimed for use in other patients

¹²²⁵ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30009-30010.

¹²²⁶ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 473-474.

- to discuss clinical priorities for use of blood in the event of blood shortages
- to report transfusion reactions
- to encourage blood donation as a community responsibility.¹²²⁷

683. The edition of *Clinical Guide to Transfusion* in use until 1987 warned about the risks inherent in transfusion:

Transfusion of blood and blood products subjects patients to risks. Clinical judgment is required to determine that the expected benefits of the transfusion outweigh these risks.¹²²⁸

In 1987, this warning was expanded:

The Blood Services of The Canadian Red Cross Society are committed to delivering to Canadian health care facilities blood and blood products of consistently high quality. Nevertheless, the nature of these products and the limitations of the techniques by which they are prepared and tested are such that the possible presence of certain infectious agents or immunizing substances cannot be universally avoided. This guide, therefore, cannot be interpreted in whole or in part as an express or implied warranty of the safety or fitness of the blood and blood products described herein even when used for their intended purposes.

Each unit of donor blood has been tested and found non-reactive for hepatitis B surface antigen (HBsAg) by an approved method of third generation sensitivity, and for the presence of antibodies to the Human Immunodeficiency Virus (HIV) by a federally approved test. A serologic test for syphilis has also been performed, and found to be negative.

Despite these efforts to reduce the risk of transmitting infectious agents, the possible presence of these agents in blood components and products cannot be avoided. There are other blood-borne infectious agents, for which adequate tests are not available, which add to the risk associated with blood transfusion. The physician and patient should consider the above risks and weigh the benefits of therapy accordingly.¹²²⁹

¹²²⁷ Ex. 539, *Supplementary Documents, Dr. Herst Cross-Examination, Tab 1, p. 1 (Clinical Guide to Transfusion, Products and Practices, First Edition, 1980)*.

¹²²⁸ *Ibid.*

¹²²⁹ Ex. 539, *Tab 1, p. 30 (Clinical Guide to Transfusion, Products and Practices, Second Edition, 1987)*.

684. CRCS medical staff were experts in transfusion medicine and the preparation of blood components. In hemophilia care, the treating physician, who has expertise in matters of blood products and treatments, is responsible for product and treatment choice for an individual patient. The CRCS did not interfere with the treating physician's advice to hemophiliacs on the mode or choice of treatment; however, they did provide advice regarding produce use on an advisory basis if requested:

...Once again, I think we have to emphasize that the treating physician is key in this. The treating physician is the one that makes the decisions and orders up the material.

It would be I think a very poor thing for the Red Cross to start to interfere in that particular relationship.¹²³⁰

A: It was always, and continues to be, the practice of the Blood Transfusion Service to supply materials which are duly licensed for use. It is the prerogative of the physician and his requirement to oversee and supervise and direct therapy.

Q: Did you think then or do you think now that there was any place for the Canadian Red Cross to interfere in the treatment between doctor and patient?

A: It had no prerogative to do so.¹²³¹

685. Treatment choices and options were based on the physician's assessment of the needs and circumstances of each patient.¹²³² Any discussion regarding an appraisal of the likelihood of possible complications and the side-effects of transfusion would have taken place between the physician and patient.¹²³³

¹²³⁰ Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, p. 8839.

¹²³¹ Evidence of Dr. Gorelick, Halifax Centre Medical Director, pp. 13159-13160.

¹²³² Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30009.

¹²³³ Evidence of Dr. Alport, former Regina Centre Medical Director, p. 8809.

686. Any risk/benefit discussion was conducted between the hemophilia treater and his or her patient. The CRCS was not privy to such discussions and was responsible for the provision of whatever licensed product was requested by the treating physician. Only on rare occasions would the CRCS question a physician's orders where it was an unusual request or appeared unwarranted:

MR. LAVIGNE: By whom?

DR. DAVEY: And in dealing with the physician, one would say: "Look, this is not what you should do." But if the physician said, "Yes, but it is what I am going to do and it is what, with my patient I have decided is in the best interest of the patient," I mean one finally said "Well, very well, Doctor, we will provide you with this product."

Now, quite clearly, if the action proposed were manifestly unsafe, hazardous, et cetera, one's protests would be loud, long and one might refuse provision. But otherwise, one respected the clinical judgment. One had to respect the clinical judgment of one's colleagues.¹²³⁴

687. As Dr. Huntsman testified, treating physicians considered themselves to be experts. One physician wrote to him after receiving unsolicited advice from a CRCS Deputy Medical Director,

'I reiterated, as I said in my previous letter, I don't need instruction from anybody about transfusion of blood. If I need help, I will ask for it'.¹²³⁵

2) Hemophilia Treatment; Product/Risk Evaluation

688. Prior to the reports of AIDS in hemophiliacs, the evaluation of the risks and benefits of any treatment would include consideration of the risks of contracting hepatitis B or non-A, non-B (as it was then called). While some physicians were hesitant to adopt concentrates once they became available due to a greater risk of contracting hepatitis, generally physicians

¹²³⁴ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30010-30011.

¹²³⁵ Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13810-13812.

and patients considered hepatitis to be an acceptable risk when balanced against the significant convenience of concentrates, improvements in one's life-expectancy and in quality of life.¹²³⁶ Even when some treating physicians were adamant about continuing a regime of cryoprecipitate, as opposed to concentrates, many hemophiliacs, although aware of the increased risk of hepatitis, and later AIDS, demanded concentrates.¹²³⁷ As Dr. Glenn F. Pierce, a physician and hemophiliac noted in the summer of 1983:

Several years ago, most of our doctors warned us we all develop inhibitors (antibodies) if we continued using blood products and bleed to death.

Ten years ago some of our doctors warned us about Hepatitis and told us we would all die from liver failure if we began using pooled lyophilized concentrates.

Today, some of our doctors are warning us about AIDS and telling us we may die from overwhelming infections if we continue using concentrates.

The hemophilia community has heard the discussions on the risks of developing AIDS...

Should we radically alter our lifestyles because of this threat? ...

¹²³⁶ Ex. 553, Vol. 127, Tab 18, p. 2 (*Open meeting of the PHS Committee on Opportunistic Infections, dated July 27, 1982*);

Evidence of Dr. Poon, Hemophilia Treater, pp. 34470-34471;

Evidence of Dr. Perrault, former National Director BTS, pp. 30237-30238;

Ex. 750, Vol. 157, Tab 57 (Paper titled "Effect of Treatment on Hepatitis B Infection and Liver Disease in Hemophilia" revised April 10, 1981, by Dr. Card, Ms. Dusevic and Dr. Lukie); and

Ex. 750, Vol. 157, Tab 3, p. 19 (Report on NIH Meeting, "Workshop on Hemophilia", dated March 1-2, 1976; by Dr. Inwood).

¹²³⁷ *Evidence of Ed Kubin, CHS, Manitoba Chapter, pp. 10338-10342;*

Ex. 222, Vol. 77, p. 1 (November 6, 1979 letter to Dr. Gerry Growe from Dr. Rayner);

Evidence of Ed Kubin, CHS, Manitoba Chapter, pp. 34661-34662;

Evidence of Dr. Rayner, Deputy Medical Director, Winnipeg Centre 1984-1988, p. 34164 and pp. 34176-34178; and

Ex. 754, Tab 28, pp. 121-123 (Dr. Glenn Pierce "The Risk of Acquired Immune Deficiency Syndrome: a Plaintiff's Perspective", Hemophilia News Notes, Summer 1983) set out in detail in paragraph 368 of this document.

What would it mean to me if I gave up concentrates and switched to cryoprecipitate? It would mean hours, not minutes, before a bleed would be controlled. It would mean hives and chills with the infusion, and a small chance of a life-threatening anaphylactic reaction. It would mean hours, maybe even a day of missed work. It would mean a loss of freedom to fly to New York or even drive to Acron. It would mean uncertainty, insecurity, and increased anxiety, knowing the emotional price of a new bleeding episode. It would mean more crippling, arthritis, and pain in my future.

It took me years to convince myself as to the advantages of treating joint bleeding rapidly... I now know what the effects of rapid control of bleeding have had in normalizing my life...

I attended the National Hemophilia Foundation (NHF) semi-annual board meeting last April and talked with some of the most successful hemophilic men in the country, all of whom carried lyophilized concentrates in their overnight bags. We argued the risk/benefit ratio of switching to cryoprecipitate or of avoiding treatment of bleeding episodes. In a rare moment of understanding for any large group of individuals, we were all in strong agreement: These men were not willing to compromise their successful life styles, given the currently understood low risk of acquiring AIDS. ...¹²³⁸

689. In early 1983, when it was uncertain whether hemophiliacs were at higher risk for developing AIDS, neither the CHS MSAC, nor the NHF MSAC, advocated any major changes to the recommended treatment for the majority of hemophiliacs.¹²³⁹ Treaters and their

¹²³⁸ Ex. 754, Tab 28, pp. 121-123 (Dr. Glenn Pierce "The Risk of Acquired Immune Deficiency Syndrome: a Plaintiff's Perspective", Hemophilia News Notes, Summer 1983).

¹²³⁹ Ex. 553, Vol. 127, Tab 20, p. 89 (Article in CCBC Newsletter by Dr. Glenn Pierce (a hemophiliac), dated August 12, 1983);

Ex. 756, Vol. 162, Tab 23, p. 3 (Letter from Frank Terpstra, Editor - Hemophilia Ontario to Dr. Strawczynski enclosing "Update on AIDS" revised February 1984, dated February 28, 1984);

Ex. 754, Vol. 160, Tab 51 (CHS Press Release, dated July 19, 1983);

Ex. 759, Vol. 165, Tab 1 (AIDS Centre News: Vol. 1, No. 3: Special Issue - WFH RIO Congress, dated November 1984);

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 29673-29675;

Ex. 759, Vol. 165, Tab 52, pp. 180-181 (Paper entitled "Heat-treated Factor VIII Concentrates - Medical Views and Implementation Strategy" by Dr. Card, dated December 10, 1984);

Evidence of Dr. Card, former MSAC Chair, pp. 31859-31860, 31862-31863; and

Ex. 753, Vol. 159, Part II, Tab 8 (Medical Director's Report to the Saskatchewan Chapter, CHS by Dr. Card, dated March 7, 1983).

patients balanced the perceived risks of continuing concentrate therapy against the profound effect cessation of concentrate use might have on the lives of many hemophiliacs. Treaters were aware that some hemophiliacs had reacted to 'sensational media reports' about AIDS with a fear which was perceived by some to be out-of-proportion to the state of knowledge and estimated risk of contracting AIDS.¹²⁴⁰ Many treaters felt they could not advise nor convince a family bread-winner to abandon concentrate therapy and threaten his family's livelihood and health. Some hemophiliacs, out of fear, had stopped treating themselves.¹²⁴¹ Failure to treat led to pain and eventual crippling. Moreover, the use of concentrates enabled a hemophiliac to undergo surgery to correct disabling problems associated with the disease that traditionally had restricted a hemophiliac to a wheelchair often resulting in his unemployment.¹²⁴² The cessation of treatment was believed to be riskier than regular use of concentrates which might expose a hemophiliac to AIDS.¹²⁴³

690. While cryoprecipitate was also associated with an inherent risk of hepatitis, the greater pool of donors necessary to manufacture concentrates increased any risk.

691. Even in the face of AIDS as the risk began to become more apparent, some hemophiliacs were extremely reluctant to return to the treatment regime of cryoprecipitate they had utilized prior to concentrates. Treaters recognized this and assented to their patient's decision regarding the assessment of the risks.¹²⁴⁴ The forgoing treatment was universally

¹²⁴⁰ Evidence of Dr. Grove, *Hemophilia Treater*, pp. 33061-33062.

¹²⁴¹ *Ibid*, pp. 33061-33062.

¹²⁴² Ex. 1058A, pp. 11-13, ("Hemophilia and Acquired Immune Deficiency Syndrome" (Transcript)) March 11, 1983.

¹²⁴³ Evidence of Bill Mindell, *CHS Member (Ontario Chapter)*, pp. 32223-32225.

¹²⁴⁴ Ex. 1058, pp. 11-13 ("Hemophilia and Acquired Immune Deficiency Syndrome" (Transcript)) March 11, 1983.

thought to be riskier than regular infusion with concentrates, particularly when it was believed that not everyone would go on to full-fledged AIDS and die.¹²⁴⁵

692. For most hemophiliacs, a return to cryoprecipitate was considered a significant set-back to the relative normalcy in their lives, which had been achieved through the use of concentrate.¹²⁴⁶ Self-infusion with cryoprecipitate was a complicated, time-consuming process, which could involve thawing numerous bags, mixing them with saline and injecting them over a period of hours several times per week.¹²⁴⁷ For a hemophiliac on home-care, cryoprecipitate use often required an additional freezer in order to maintain the plasma derivatives at an acceptable temperature (as a conventional kitchen freezer was unable to maintain cryoprecipitate at the requisite freezing point).¹²⁴⁸ Most hemophiliacs, however, on cryoprecipitate had the treatment administered at hospitals. This meant that severe hemophiliacs who had several bleeds per week had great difficulty with regular school attendance and employment. Moreover, as cryoprecipitate was a less purified product there was risk of allergic reactions following infusion. The most serious reaction could be anaphylactic shock which could lead to cessation of breathing and death, unless adrenaline was immediately administered.¹²⁴⁹

¹²⁴⁵ Evidence of Bill Mindell, CHS Member (Ontario Chapter), pp. 32223-32225.

¹²⁴⁶ Evidence of Dr. Grawe, Hemophilia Treater, pp. 33067-33068;

Ex. 1058 ("Hemophilia and Acquired Immune Deficiency Syndrome" March 11, 1983 (Transcript)) pp. 11-13.

¹²⁴⁷ Evidence of G. Belanger, French Nurses Panel, pp. 34819-34827.

¹²⁴⁸ Ex. 1058 p. 14 ("Hemophilia and Acquired Immune Deficiency Syndrome" March 11, 1983 (Transcript));

Evidence of Mrs. Landry, CHS Panel (NB) p. 11459; and

Evidence of Dr. MacKay, Medical Director, Saint John, New Brunswick, pp. 11958-11959.

¹²⁴⁹ Evidence of Barry Isaac, p. 7046;

Ex. 754, Tab 28, p. 122 (Dr. Glenn Pierce "The Risk of Acquired Immune Deficiency Syndrome: A Patients Perspective", Hemophilia News Notes, Summer 83);

Evidence of Dr. Moisey, Pediatrician, Hemophiliac Treater, p. 3512; and

Evidence of Ed Kubin, CHS, Manitoba Chapter, pp. 10342-10344.

693. It was known that the CRCS would provide whatever licensed product was requested by treating physicians. Despite its offer in the winter of 1983 to divert plasma from concentrate production in order to increase cryoprecipitate production, very few patients switched back from concentrate to cryoprecipitate.¹²⁵⁰ Hemophiliacs in the United States were also reluctant to switch back to cryoprecipitate.¹²⁵¹

694. For the most part, hemophilia treaters did not recommend that severe hemophiliacs return to cryoprecipitate. Another reason was that treaters did not believe that switching back to cryoprecipitate would make any difference:

MS. PAYNE: In terms of keeping the severe hemophiliacs on concentrate in - is it your recollection that the reason why the severe hemophiliacs were not taken off the concentrates (in March 1983) was in part due to an assumption that they were already likely infected with whatever agent it was that was causing AIDS?

DR. KOBRINSKY: I think that is fair, yes.¹²⁵²

695. Hemophiliacs were considered by treaters to be sophisticated patients. Many were very knowledgeable in their own treatment and care and took it upon themselves to keep

¹²⁵⁰ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 26417, 26541-26542 and 27406;

Ex. 754, Vol. 160, Tab 16, pp. 55-56 (Ontario Chapter MSAC Meeting, dated May 13, 1983);

Ex. 807, Vol. 183, Tab 14 (Letter from Dr. Stout to Dr. Growe re: Cryoprecipitates and Factor VIII, dated June 27, 1983);

Ex. 752, Vol. 159, Part I, Tab 21 (Excerpt from Minutes of the BTS, Hamilton Centre and Hamilton-Niagara Regional Hemophilia Centre Meeting, dated January 26, 1983);

Ex. 512, Vol. 115, Part I, p. 241 (Memo from Dr. Kaegi to Blood Bank Directors and Directors of Hemophiliac Clinics re: Cryoprecipitate and Factor VIII Concentrate Supplies, dated July 6, 1983);

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, p. 8698.

¹²⁵¹ Evidence of Dr. Francis, Epidemiologist, p. 22065;

Ex. 1058 pp. 11-13 ("Hemophilia and Acquired Immune Deficiency Syndrome" March 11, 1983 (Transcript)).

¹²⁵² Evidence of Dr. Nathan Kobrinsky, Hemophilia Treater, p. 34210.

informed about advances and changes in their treatment.¹²⁵³ They looked to their treating physicians and the CHS and its MSAC for information about treatment options and AIDS. Many hemophiliacs were so knowledgeable about their disease, they often second-guessed their physicians regarding the treatment advice they were given. This was obvious when many hemophiliacs demanded that their physicians prescribe concentrates for them instead of cryoprecipitate.¹²⁵⁴ In turn, physicians at the hemophilia treatment clinics encouraged patient autonomy and trained hemophiliacs to manage their own care as much as possible.¹²⁵⁵

696. Hemophilia treaters considered it inappropriate for CRCS medical staff to advise them on treatment protocols for their patients.¹²⁵⁶ Since the CRCS had no direct contact with patients,¹²⁵⁷ distributed concentrates to hospitals, and not directly to patients¹²⁵⁸, it had to rely on the hospitals and physicians to keep adequate records of product distribution in case of recalls or patient follow-up.

¹²⁵³ Evidence of Dr. Moisey, Pediatrician, Hemophiliac Treater, p. 32437; and

Evidence of Dr. Furesz, BoB Panel, pp. 43477-43478.

¹²⁵⁴ Evidence of Dr. Strawczynski, Montreal Children's Hospital, p. 31355;

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10029-10030;

Evidence of Ed Kubin, CHS, Manitoba Chapter, pp. 10338-10342; pp. 34661-34662; and

Evidence of Ken Poyser, former Chair of the CHS Blood Resources Committee, pp. 32166-32167.

¹²⁵⁵ Evidence of Dr. Growe, Hemophiliac Treater, pp. 33064-33065.

¹²⁵⁶ Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31386;

Evidence of Dr. MacKay, Saint John Centre Medical Director, pp. 11760-11761; and

Ex. 750, Vol. 157, Tab 22 (Letter from Dr. Derrick to Dr. King, dated November 27, 1978).

¹²⁵⁷ Evidence of Dr. Perrault, former National Director BTS, p. 29574.

¹²⁵⁸ The only exception is the case of the Winnipeg Centre which also runs the hospital blood bank according to Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10007-10008.

Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13973-13974.

697. The CRCS medical director's involvement ended on the components or plasma derivatives ordered were distributed to the requesting physician or hospital. As stated above, the final decision over whether to use blood therapy rested with the clinician and hospital facility in consultation with the patient.¹²⁵⁹

I know this has been a contention of hemophiliacs all along, that somebody should have told them something, but I think that -- we talked about learned intermediaries yesterday in terms of who has the obligation to notify patients, and I think in our country, generally, it is the physician, the treating physician. If he reads the literature, or she reads the literature, and they take care of the patient, it's in -- I think generally held that it is the responsibility of the treating physician to make contact with the patient, and not the manufacturer of the product or service.¹²⁶⁰

3) Canadian Hemophilia Society

698. The mandate of the CHS was to develop, monitor, evaluate, initiate and promote all blood product issues in Canada and to provide information to all users.¹²⁶¹ The CHS and physicians encouraged hemophiliacs to visit their treating physicians regularly and to join their local chapter of the CHS, which would also provide them with information.¹²⁶² In addition,

¹²⁵⁹ Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13810-13816;

Ex. 334, Vol. 99, p. 300 (Letter from unnamed Hemophilia Treater, copied to Dr. Huntsman, dated May 6, 1983);

Evidence of Drs. Perrault and Davey, pp. 26655-26656, 27250-27251; and

Evidence of Dr. Francis, Epidemiologist, p. 22079.

¹²⁶⁰ Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22738.

¹²⁶¹ Ex. 761, Vol. 167, Tab 7, p. 28 (Letter from R.W. Rudd to Board of Directors, March 2, 1985 enclosing the Draft CHS Blood Products Policy).

¹²⁶² Evidence of Ed Kubin, CHS Manitoba Chapter, pp. 34587-34588; and

Evidence of Dr. Carci, former MSAC Chair, p. 31923-31925.

members of the CHS were in direct contact with the fractionators and visited each of the fractionation plants.¹²⁶³

699. The terms of reference of the CHS MSAC included its mandate to "offer counsel and assistance to the CHS and guidance to other concerned bodies on medical, scientific and professional matters pertaining to the care of hemophiliacs".¹²⁶⁴ Its duties included the drafting of recommendations concerning all components of the comprehensive management of hemophilia, initiating appropriate action to ensure that all hemophiliacs received an optimum level of care, as well as cooperation with the CHS, the CRCS, governmental and private agencies in addressing issues of importance relating to the welfare of patients with hemophilia.¹²⁶⁵

700. The MSAC functioned as the expert advisory body to provide information on hemophilia treatment to all hemophiliacs and their family members.¹²⁶⁶ The CHS MSAC members were frequently engaged in correspondence and telephone contact with other major players in the blood system including the CBC and the CRC.¹²⁶⁷

701. The CHS was a unique consumer group. It kept in touch with its international counterparts, such as the National Hemophilia Foundation (hereinafter referred to as "NHF") in the United States. These two groups met two to three times a year to share information and

¹²⁶³ Evidence of Ed Gurney, former Executive Director of the CHS pp. 32966-32973; and

Exhibit 754, Volume 160, Tab 62 (Letter from M. Poyer to K. Poyer, dated August 11, 1983).

¹²⁶⁴ Ex. 754, Vol. 160, Tab 30, p. 131 (Canadian Hemophilia Society Medical and Scientific Advisory Committee - Terms of Reference, June 1983).

¹²⁶⁵ Ibid, p. 131.

¹²⁶⁶ Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8666-8667 and pp. 8749-8750.

¹²⁶⁷ Evidence of Dr. Card, former MSAC Chair, pp. 31527-31529; and

Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31083-31084.

discuss matters of mutual concern.¹²⁶⁸ In addition, the CHS received all mailings and publications from both the NHF as well as the WHF.¹²⁶⁹

702. Some lay CHS members were extremely knowledgable in the treatment of hemophilia. Ken Poyer, former Chair of the CHS Blood Resources Committee, for example, attended the World Federation of Hemophilia Conference in Stockholm in the summer of 1983 where many important issues concerning AIDS and hemophilia were discussed at great length.¹²⁷⁰ Likewise, Linda Laxdal (former President of the CHS) and Ed Gurney (former Executive Director) attended the 1984 World Hemophilia Congress in Rio di Janeiro the following year.¹²⁷¹ Attendance at such sessions where information was exchanged was common. Accordingly, as attendees at these important forums, the CHS were parties to the same information on advances and changes to hemophilia treatment, AIDS and other conditions as were the treaters and CRCS personnel who attended.

703. Dr. Card, former Chair of the CHS MSAC testified that at his hemophilia treatment clinic a CHS volunteer would attend each session to assist physicians and meet with each patient to ensure that all patients, even those who attended infrequently, would receive CHS mailings and the publication of *Hemophilia Today*.¹²⁷²

¹²⁶⁸ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32958-32959.

¹²⁶⁹ Evidence of Ed Gurney, former Executive Director of CHS, p. 32961.

¹²⁷⁰ Ex. 756, Vol. 162, Tab 62, p. 224 (*Blood Resources Committee Report*, dated April 12, 1984)

[After attending Stockholm, Bill Rudd, former President of the CHS, urged hemophiliacs not to change their treatment regime in November the November 1983 edition of "Hemophilia Today" Ex. 28, Volume 10, p. 2168 "Hemophilia Today" November 1983]

¹²⁷¹ Ex. 758, Vol. 164, Tab 11, p. 54 (Confidential Memorandum from Dr. Naylor to Drs. Perrault and Davey, dated September 13, 1984).

¹²⁷² Evidence of Dr. Card, former MSAC Chair, pp. 31923-31924.

704. Membership of the CHS is open to all family and friends of hemophiliacs. There were no dues or fees for joining.¹²⁷³ Those lay participants, such as members of the Blood Resources Committee, active in the CHS were considered by treaters as knowledgeable and sophisticated individuals.¹²⁷⁴ Moreover, many of the senior people in the CHS had impressive global contact with hemophilia experts. Bill Mindell, for example, was in communication with Drs. Aledort and Chan of the NHF MSAC.¹²⁷⁵ Mr. Frank Schnabel, a senior member of the CHS and later head of the WHF, was in regular contact with the leading world hemophilia treaters, including Drs. Aledort, Levine and Shelby in addition to other contacts with international hemophilia advocacy groups and treaters. They received information from as far away as Sweden and the Netherlands.¹²⁷⁶ Mr. Schnabel met with senior executives and representatives of the various fractionators and biologics companies including Cutter, Hyland, and Genetech on a regular basis.¹²⁷⁷

705. The CHS and its members never hesitated to relay their concerns to the CRCs or government. The CHS therefore was not only an informational body but a powerful lobby group which was actively involved in shaping Canadian blood policy.¹²⁷⁸

¹²⁷³ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32894-32895.

¹²⁷⁴ Evidence of Ed Gurney, former Executive Director of CHS, p. 32975; and

Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31083-31084.

¹²⁷⁵ Ex. 760, Vol. 166, Tab 10 (January 16, 1985 Letter from Louis Aledort to Bill Mindell).

¹²⁷⁶ Ex. 752, Vol. 159, Part 1, Tab 49 (February 26, 1983 Letter to WFH - Martha Schnabel from Paul de Guaf); and

Evidence of Ken Poyser, former Chair of the CHS Blood Resources Committee, p. 31951.

¹²⁷⁷ Ex. 753, Vol. 159, Pt. II, Tab 35, p. 1 (April 19, 1983 Memo to WFH Council from Frank Schnabel).

¹²⁷⁸ Evidence of Dr. Strawczynski, Montreal's Children's Hospital, pp. 31083-31084;

Ex. 750, Vol. 157, Tab 40 (September 15, 1980 Letter to Dennis Timbrell from Ken Poyser);

Ex. 750, Vol. 157, Tab 42 (September 18, 1980 Letter to Ken Poyser from Dennis Timbrell);

Ex. 754, Vol. 160, Tab 37 (June 13, 1983 Letter to Ken Poyser from J. Furesz);

706. The CRCS gave serious consideration to the concerns of the CHS and its membership. On many occasions recommendations were adopted. Lay members of the CHS monitored concentrate quality¹²⁷⁹ and lobbied for those concentrates which they wanted to be made available to hemophiliacs.

707. In mid-1985 Bill Mindell and other members of the Ontario Chapter of the CHS lobbied the National MSAC and the CRCS to supply cryoprecipitate manufactured solely from female donors, suggesting that such cryoprecipitate would be "safer".¹²⁸⁰ As Canada was in the midst of switching to heat-treated concentrates and testing was expected to be implemented within the year, Mr. Mindell forwarded this proposal for consideration as a temporary measure pending testing and heat treatment.¹²⁸¹

Ex. 750, Vol. 157, Tab 43 (September 23, 1980 Letter to The Honourable Monique Begin from Dr. Growe Chair MSAC);

Ex. 750, Vol. 157, Tab 44 (September 23, 1980 Letter to Monique Begin from Ken Poyer);

Ex. 750, Vol. 157, Tab 45 (September 23, 1980 Letter from Dennis Timbrell from Ken Poyer, President CHS);

Ex. 750, Vol. 157, Tab 46 (September 26, 1980 Letter to Dennis Timbrell from Frank Terpstra President CHS Ontario);

Ex. 750, Vol. 157, Tab 48 (November 6, 1980 Letter to Dr. Chapin Key from Dr. Growe - CHS MSAC);

Ex. 750, Vol. 157, Tab 49 (November 13, 1980 Letter to Dennis Timbrell from Frank Terpstra);

Ex. 750, Vol. 157, Tab 50 (December 18, 1980, Letter to Monique Begin from Ken Poyer); and

Ex. 750, Vol. 157, Tab 52 (December 30, 1980, Letter to Dr. Chapin Key from Dr. Growe).

¹²⁷⁹ As discussed *infra*.

¹²⁸⁰ Evidence of bill Mindell, CHS Member (Ontario Chapter), pp. 32250-32356;

Ex. 759, Vol. 165, Tab 45 (Memo from Bill Mindell to Ontario and national CHS Factor Products/Blood Products Committees, dated December 8, 1984); and

Ex. 760, Vol. 166, Tab 21, p. 69 (Letter to the editor of the Lancet, dated January 12, 1985).

¹²⁸¹ *Ex. 759, Vol. 165, Tab 39 (Memo to file from Dr. Naylor re: Cryoprecipitate from Female Donors, dated December 6, 1984); and*

Ex. 759, Vol. 165, Tab 63 (Letter from Dr. Walker to Dr. Card, dated December 17, 1984).

708. This suggestion was fully canvassed by both the Ontario and National CHS MSAC's, the Factor/Blood Products Committees, the Ontario Fractionator/Supplier/User Group, the Blood Components Working Group, and the CRCS Medical Directors.

709. The concept of producing cryoprecipitate manufactured exclusively from female donors was ultimately not favoured by the CHS MSAC or the CRCS.¹²⁸² It posed several logistical problems, including the difficulty in maintaining an adequate supply, in light of the fact that the majority of blood donors were men. In addition, it was not certain that female donors had a lower HIV seroprevalent rate than male donors.¹²⁸³ Dr. Card and Dr. Walker, of the CHS MSAC as well as Dr. Clayton of the LCDC testified that they did not agree with the proposition.¹²⁸⁴ Other witnesses during the Inquiry also commented on the ethical problem that would have arisen had components manufactured from female donors been provided to some patients and not to others.¹²⁸⁵

¹²⁸² Ex. 633, CRC Vol. 30, Tab 19 (*Minutes, Medical Directors Committee Meeting, dated March 27-28, 1985*);

Ex. 761, Vol. 167, Tab 57 (Trip Report by Dr. Naylor re: MSAC Meeting, dated April 19, 1985);

Ex. 761, Vol. 167, Tab 53 (Minutes, National MSAC Meeting, dated April 19, 1985); and

Ex. 763, Vol. 169, Tab 48 (Memo from Dr. Naylor to file, dated August 8, 1985).

¹²⁸³ Ex. 637, Vol. 34, Tab 12, p. 76429 (June 20, 1985 Letter to Dr. Card from Dr. Naylor re: Relevance of HTLV-III Antibodies in blood donors).

¹²⁸⁴ Ex. 763, Vol. 169, Tab 7 (*Letter from Dr. Naylor to Dr. Card, dated June 20, 1985*);

Ex. 759, Vol. 165, Tab 69 (Letter from Bill Mindell to Dr. Clayton, dated December 27, 1984);

Ex. 761, Vol. 167, Tab 51 (Memo from Dr. Davey to Dr. Naylor, dated April 18, 1985);

Ex. 760, Vol. 166, Tab 15 (Letter from Dr. Card to Mr. Bill Rudd, dated January 28, 1985);

Evidence of Dr. Card, former MSAC Chair, pp. 31874-31878; and

Evidence of Bill Mindell, CHS Member (Ontario Chapter), pp. 32270-32274, 32311.

¹²⁸⁵ Ex. 796 (*Memo from Pat Humphreys to Dr. Davey, dated January 17, 1985*); and

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22705-22706.

710. John Petricciani, Director of the FDA Blood and Blood Products Division, reported that American tests had revealed the prevalence of antibodies to HTLV-III was roughly equal in men and women. Consequently, Dr. Petricciani agreed that there was no logic in producing blood components exclusively from female donors.¹²⁸⁶

711. Individual members of the CHS were in direct contact with the fractionators and even visited the fractionation plants.¹²⁸⁷ One of the more vocal bodies involved in monitoring concentrate purchases was the CHS Blood Resources Committee consisting primarily of CHS lay members. Its role was to review contracts with fractionators and report to the CHS. Members of the committee were sophisticated and very knowledgeable about blood products.¹²⁸⁸ They had direct contact with all of the fractionators and were frequently lobbied by them to purchase concentrates.¹²⁸⁹ Moreover, CHS members contacted the fractionators to request funding or discuss product issues.¹²⁹⁰

712. The CHS representatives stated that they were "in constant contact with every fractionating company...",¹²⁹¹ including Travenol, Cutter, Connaught and occasionally Armour

Evidence of Dr. Card, former MSAC Chair, pp. 31874-31878;

Evidence of Bill Mindell, CHS Member (Ontario Chapter), pp. 32347-32349.

¹²⁸⁶ Ex. 637, Vol. 34, Tab 12, p. 76429 (June 20, 1985 Letter to Dr. Card from Dr. Naylor re: Relevance of HTLV-III Antibodies in blood donors).

¹²⁸⁷ *Evidence of Ed Gurney, former Executive Director of CHS, pp. 32966-32973; and*

Ex. 754, Vol. 160, Tab 62 (Letter from M. Posner to Ken Poyser, dated August 11, 1983).

¹²⁸⁸ *Evidence of Ed Gurney, former Executive Director of CHS, pp. 32974-32975.*

¹²⁸⁹ *Evidence of Ed Gurney, former Executive Director of CHS, p. 32989.*

¹²⁹⁰ *Evidence of Ed Gurney, former Executive Director of CHS, pp. 32989-32990.*

¹²⁹¹ Ex. 755, V. 161, Tab 67 (Letter to Jack Soberman from Ed. Gurney, dated November 18, 1983); and

Evidence of Ed Gurney, former Executive Director of CHS, p. 32925, 32971.

and Alpha.¹²⁹² In January 1984, Bill Mindell and Jo-anne Harpur of the CHS met with Drs. Mercer, Wah and Kim at the CLL plant and toured CLL's manufacturing facilities.¹²⁹³

713. In addition, the CHS regularly received funding from the fractionators including Cutter, Travenol and Connaught for its various projects in the amounts of thousands of dollars.¹²⁹⁴

4) Hemophilia Treaters

714. The physicians who entered the field of hematology and hemophilia treatment are medical specialists. As specialists, they are expected to keep abreast of any and all advances in and changes to hemophilia treatment protocols, as would any other physician specializing in a particular field or area.¹²⁹⁵

715. Hemophilia treaters received information on treatment from many sources including the CHS, the WHF, and the NHF. Treating physicians traditionally kept up with scientific developments as reported in such journals the *New England Journal of Medicine*, *Transfusion*, and *Vox Sanguinis*. They attended scientific symposiums and conferences and consulted with other physicians and clinical experts.¹²⁹⁶ Their attendance at numerous conferences held on the subject of hemophilia enabled them to upgrade their skills further in

¹²⁹² Evidence of Ed Gurney, former Executive Director of CHS, pp. 32970-2.

Ex. 758, Vol. 164, Tab 31, pp. 130-131 (Minutes of Executive Committee Meeting - Canadian Hemophilia Society, October 20, 1984).

¹²⁹³ Ex. 756, Vol. 162, Tab 10 (February 8, 1984, Visit to Connaught Laboratories January 20, 1984.)

¹²⁹⁴ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32878-32881.

¹²⁹⁵ Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8806-8807.

¹²⁹⁶ Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31414-31415; and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30243-30244.

addition to their ongoing clinical and academic training.¹²⁹⁷ The CHS MSAC was made up primarily of treating physicians which reported to all other treating physicians.

716. The CRCS relied upon hemophilia treaters to communicate with them about which products they would like to use for the treatment of their patients. Subject to licensure, the CRCS distributed whatever product was requested by hemophiliacs and their treaters.¹²⁹⁸ As experts in this field with a direct relationship with their patients, hemophilia-treating physicians had exclusive knowledge of the needs of their patients. The majority of treaters are hematologists and are therefore well-versed and knowledgeable about the range of products available to treat their patients' disease.¹²⁹⁹ Virtually all treating physicians have clinical and specialized training in hematology and coagulation as well as significant laboratory experience in coagulation assays. They have often conducted their own laboratory and clinical studies on plasma derivatives.¹³⁰⁰ Hemophilia treaters in Ontario for example, were deeply involved in clinical trials for many heat-treated concentrates.¹³⁰¹ Treating physicians evaluated various plasma derivatives independently and did not rely solely on the CRCS for information on concentrates and efficacy in terms of treatment. For example, Drs. I. Walker and Pai were involved with the evaluation of the Armour, Cutter, RH Institute and Cutter heat-treated

¹²⁹⁷ Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31414-31415; and

Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22522-22524.

¹²⁹⁸ Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 10021-10022;

Evidence of Dr. Mackay, Saint John Centre Medical Director, pp. 11756-11757; and

Evidence of Dr. Buskard, former Vancouver Centre Medical Director, p. 5613.

¹²⁹⁹ Evidence of Dr. Perrault, former National Director BTS, p. 27251.

¹³⁰⁰ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 26655-26657.

¹³⁰¹ Ex. 760, V. 166, Tab 3 (Letter to Dr. Naylor from Dr. I. Walker, dated January 7, 1985).

For a full discussion of heat-treatment, see Section III F Heat Treatment of this document.

concentrates.¹³⁰² A trial of Porcine Factor VIII concentrate was undertaken by Dr. Card and the Hemophilia Treatment Centres.¹³⁰³ Moreover, the fractionators regularly contacted treating physicians to make them aware of changes or advances in products and lobbied them to use their particular concentrate.¹³⁰⁴

717. Hemophilia treaters had direct input into the process by which concentrates were licensed and selected by the CRCS for use in Canada.¹³⁰⁵ Physicians were also in contact with the BoB and made it known which concentrates they would like to use to treat their patients.¹³⁰⁶

¹³⁰² Ex. 760, V. 166, Tab 3 (*Letter to Dr. Naylor from Dr. I Walker, dated January 7, 1985*);

Ex. 762, Vol. 168, Tab 11, pp. 74-75 (*Minutes of Hamilton-Niagara Regional Hemophilia Centre and Red Cross Committee Meeting, dated May 8, 1985*);

Ex. 762, Vol. 168, Tab 14 (*Memo from Dr. Naylor to File re: Armour Heat Treated Factor VIII Concentrate, dated May 9, 1985*);

Ex. 762, Vol. 168, Tab 15 (*Memo from Dr. Naylor to File re: Cutter Heat Treated Factor VIII Concentrate, dated May 9, 1985*);

Ex. 762, Vol. 168, Tab 38 (*Memo from Dr. Naylor to File re: Clinical Trial of Heat Treated Coagulation Factor Products, dated May 27, 1985*)

Ex. 762, Vol. 168, Tab 41 (*Clinical Trial Protocol for Heat Treated Factor IX Concentrate, dated May 28, 1985*); and

Ex. 762, Vol. 168, Tab 43 (*Letter to Dr. Maquin from Dr. Naylor re: Clinical Trial Protocol for heat treated Factor VIII Concentrate Factor IX Complex, dated May 30, 1985*).

¹³⁰³ Ex. 762, Vol. 168, Tab 16 (*Memo from Dr. Naylor to File re: Speywood Hyate-C, dated May 9, 1985*).

¹³⁰⁴ Evidence of Micheline Pinard, Sales Representative, Hyland/Baxter/Fenwal Corp., pp. 38949-38951; and Evidence of Jack Ryan pp. 38659-38660.

¹³⁰⁵ Ex. 755, Vol. 161, Tab 84 (*Letter to Dr. Naylor from Dr. H. Strawczynski, Chair CHS MSAC, dated December 23, 1983*); and

Ex. 755, Vol. 161, Tab 74 (*Memo from Dr. Naylor to Dr. Davey re: Porcine Factor VIII (Hyate:C)/Patients with Factor VIII Inhibitors, dated December 6, 1983*).

¹³⁰⁶ Evidence of Dr. Davey, former Assistant National Director BTS, p. 29694;

Evidence of Dr. Furesz, BoB Panel, pp. 43042-43; and

Evidence of Dr. Blanchette, Deputy Medical Director, Toronto Centre, pp. 33963-4.

718. As the community of hemophilia treaters in Canada is small, they have developed an effective network of communication among themselves and rely upon each other to share their knowledge and expertise.¹³⁰⁷

5) Communication Between Parties

719. There was ongoing discussion and communication about issues relevant to the treatment of hemophilia and the risk of disease throughout the 1980's.¹³⁰⁸ Treating physicians consulted with infectious disease specialists such as Dr. Tsoukas, who attended CHS MSAC meetings to provide information gathered from his studies of immune function in hemophiliacs.¹³⁰⁹ This tradition of consultation was maintained and strengthened throughout the 1980's as the risk to hemophiliacs and recipients of blood products became more apparent.¹³¹⁰ Experts consulted by Dr. Strawczynski, included Dr. Evatt of the CDC, Dr. Aledort, Dr. Bloom from Wales, Dr. Britain from Geneva, Dr. Kasper from Los Angeles, Dr. Dietrich from Los Angeles, - all renowned experts in blood banking, hematology and coagulation.¹³¹¹ Individual treating physicians consulted their own local experts.¹³¹²

¹³⁰⁷ Evidence of Dr. Card, former MSAC Chair, p. 31921.

Evidence of CHS Panel (Mr. Isaac) pp. 7013-7015.

¹³⁰⁸ Evidence of Dr. Card, former MSAC Chair, p. 31880; and

Ex. 755, Vol. 161, Tab 1 (Memo to all MSAC members from Dr. Strawczynski, Chair of MSAC, dated September 1983).

¹³⁰⁹ Evidence of Dr. Davey, former Assistant National Director BTS, pp. 26655-26656.

¹³¹⁰ Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31127-31128 and 31413-31416.

¹³¹¹ Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31414-31415.

¹³¹² Evidence of Dr. Card, former MSAC Chair, pp. 31834-31836.

720. There were numerous instances in which both the CHS lay members and the hemophilia treaters were involved in consultation with other players in the blood system.¹³¹³ Hemophilia-treating physicians were frequently contacted by concentrate manufacturers and provided with information on both licensed and unlicensed products.¹³¹⁴ The following are some examples:¹³¹⁵

- Ken Poyer lobbied Dennis Timbrell, the Ontario Minister of Health with respect to reports that Ontario was interfering with existing and proposed contracts between CRCS and Cutter. Mr. Poyer and the CHS did not support the move to divert plasma to Connaught for fractionation.¹³¹⁶
- Ed Gurney of the CHS requested a status report on the provision of Autoplex from Don McNaught of the Federal/Provincial Budget Review Committee.¹³¹⁷ Initially, Federal Provincial Committee members, then CBC representatives provided the CHS with regular updates on whether Autoplex would be introduced in Canada and funded by the CBC.¹³¹⁸

¹³¹³ Evidence of Dr. Card, former MSAC Chair, pp. 31527-31528.

¹³¹⁴ Evidence of Micheline Pinard, Sales Representative, Hyland/Baxter/Fenwal Corp., pp. 38943 and 38948-38951; and

Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31305-31306.

¹³¹⁵ Note that many of these examples are more fully discussed in other sections of this document in context.

¹³¹⁶ Ex. 750, Vol. 157, Tab 40 (Letter from Ken Poyer to Dennis Timbrell, dated September 15, 1980).

¹³¹⁷ Ex. 751, Vol. 158, Tab 2 (Letter from Don McNaught to Ed Gurney, dated February 2, 1982).

¹³¹⁸ Ex. 751, Vol. 158, Tab 2 (Letter to Ed Gurney from Don McNaught re: Autoplex, dated February 2, 1982); and

Ex. 751, Vol. 158, Tab 13 (Letter to Ed Gurney from Ambrose Hearn, dated March 30, 1982).

- In December, 1981, Dr. Gerry Growe and Dr. Martin Inwood re-affirmed the CHS MSAC position that Autoplex was to be made available only under strict control of the MSAC and that the CRCS should monitor and distribute Autoplex.¹³¹⁹
- In the fall of 1984, members of the CHS, Blood Resources Committee arranged and met with a number of the fractionators including, Cutter, Travenol, Connaught and Armour.¹³²⁰
- In April 1985 a representative of Alpha Pharmaceuticals wrote to Dr. Card, then Chair of the CHS MSAC, to provide him with information concerning Alpha's new heat-treated concentrates. Alpha offered to provide these concentrates to Dr. Card and included ordering information as well as guidance on where to obtain further information on viral inactivation.
- In March, 1986, the CHS MSAC contacted the CBC secretariat and requested a review of the status the HTLV-III antibody testing and demanded that the CBC provide funding to implement such testing.¹³²¹
- Following the May 3, 1986 CHS MSAC meeting, Dr. Inwood contacted the CRCS concerning MSAC's request that steam-heated Factor VIII be distributed as part of a Canadian clinical trial.¹³²²

¹³¹⁹ Ex. 750, Vol. 157, Tab 74 (Appendix 2 - CHS Motion moved by Dr. Inwood, December 17, 1981 re: Use of Autoplex).

¹³²⁰ Ex. 758, Vol. 164, Tab 9 (Report of Blood Resources Committee dated September 11, 1984).

¹³²¹ Ex. 761, Vol. 167, Tab 14 (Letter from Dr. Card to Dr. Leclerc-Chevalier, dated March 14, 1985); and

Ex. 762, Vol. 168, Tab 20 (Memo from Dr. Naylor to Drs. Perrault and Davey re: CHS Recommendations to the CRC BTS, dated May 10, 1985).

¹³²² Ex. 766, Vol. 172, Tab 18, pp. 103-104 (Minutes of CHS MSAC Meeting, dated May 3, 1986).

- Dr. Kaiser Ali lobbied Jake Epp, the Federal Health Minister in 1988 concerning the procurement of enhanced virally inactivated concentrates.¹³²³
- Representatives of Travenol met regularly with CHS members such as Ken Poyer, at the CHS national office and many other hemophilia conferences and symposiums.¹³²⁴
- Travenol company representatives met with CHS members on an ongoing basis to discuss product availability and advances in treatment research.¹³²⁵
- Travenol representatives were in regular contact with many of the treating physicians including Drs. Strawczynski, Rivard, Inwood, Herst and Card and supplied them with information on Hemophil T - heat treated concentrate, Autoplex and a wide range of other Travenol plasma derivatives.¹³²⁶

6) CHS Registry

721. The CRCS was responsible for monitoring trends on the utilization of blood and plasma products in order to anticipate future needs.¹³²⁷ In order to better anticipate and meet the needs of Canadian hemophiliacs, the CRCS urged the CHS and the Hemophilia Treatment Centres to develop a Canada-wide registry and census of hemophiliacs. The first CHS census

¹³²³ Ex. 772, Vol. 178, Tab 9 (*Letter from Dr. Kaiser Ali to Jake Epp, dated May 30, 1988*).

¹³²⁴ Evidence of Micheline Pinard, Sales Representative, Hyland/Baxter/Fenwal Corp., pp. 38944-38946; and Evidence of Ken Poyer, former Chair of the CHS Blood Resources Committee, pp. 31991-31992.

¹³²⁵ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32926-32932; and Evidence of Micheline Picard, pp. 38948-38951

¹³²⁶ Evidence of Micheline Pinard, Sales Representative, Hyland/Baxter/Fenwal Corp., pp. 38958-38960 and pp. 38949-38951.

¹³²⁷ See Section II A, *The Delicate Balance Between Supply and Demand: Shortages and Over-Utilization*.

was completed in 1978.¹³²⁸ By 1983 it was incomplete and out-of-date and accordingly, the CRCS requested updated statistics from the CHS representatives on the number of Canadian Hemophiliacs.¹³²⁹

722. Following its 1978 census the CHS had planned to undertake a more extensive and up-to-date census. They ultimately sought to develop a registry of hemophiliacs which would serve to provide the CRCS with much-needed updated information on the needs and treatment habits of Canadian hemophiliacs.¹³³⁰ The "Integrated Information System" or IIS

¹³²⁸ Ex. 750, Vol. 157, Tab 14, pp. 78-80, 92 (*The Canadian Hemophiliacs and Their Need for Blood Fractionation*); and

Evidence of Ed Gurney, former Executive Director of CHS, pp. 32866-32867.

¹³²⁹ Ex. 758, Vol. 164, Tab 11 (*Memo from Dr. Naylor to Drs. Perrault and Davey, dated September 13, 1984*);

Ex. 753, Vol. 159, Part II, Tab 18 (*Letter from Dr. Naylor to Ed Gurney re: 1983 Requirements of Factor VIII/Source of Product, dated March 21, 1983*);

Ex. 757, Vol. 163, Tab 13 (*Letter from Dr. Naylor to Dr. Rivard, dated May 9, 1984*);

Ex. 758, Vol. 164, Tab 30, p. 2 (*Summary of a Meeting between CHS and CRC National BTS Representatives, dated October 19, 1984*);

Ex. 751 Vol. 158, Tab 25 (*Letter to Dr. Davey from Dr. Martin Inwood re: Use of Factor VIII and IX Concentrates*); and

Ex. 754, Vol. 160, Tab 16 (*Minutes of the CHS MSAC Meeting, dated May 13, 1983*).

¹³³⁰ Ex. 758, Vol. 164, Tab 11 (*Summary of an Informal Meeting held with Representatives of the Canadian Hemophilia Society, dated September 13, 1984*);

Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31209-31210;

Ex. 753, Vol. 159, Part 2, Tab 18 (*Letter to Ed Gurney from Dr. Naylor re: 1983 Requirements of Factor VIII/Source of Product, dated March 21, 1983*);

Ex. 757, Vol. 163, Tab 8, p. 7 (*Minutes of the CHS Annual General Meeting and Board of Directors Meeting, dated May 5 and 6, 1984*);

Ex. 757, Vol. 163, Tab 13 (*Letter to Dr. Rivard from Dr. Naylor, dated May 9, 1984*);

Ex. 758, Vol. 164, Tab 30, p. 2 (*Summary of Meeting Between Canadian Hemophilia Society and CRC National BTS Representatives, dated October 19, 1984*);

was first described in May 1978 at a workshop conference in Winnipeg. CHS members from all provincial and national chapters agreed that the head office of the CHS should be linked with all major comprehensive hemophilia programmes across the country.¹³³¹

723. A nationwide registry or database listing the number of hemophiliacs, the severity of their condition, their treatment regime and any comprehensive clinic in which they had registered would have enabled treaters to account for and monitor all product use. Problems with over and under utilization of concentrate or cryoprecipitate could have been quickly identified and corrected.¹³³² Such a national registry would also have assisted the CRCS in inventory planning, supplementary purchase planning, concentrate and cryo production, and distribution of plasma derivatives for use in the treatment of hemophilia and related conditions. In addition, it would have greatly facilitated the prompt notification of hemophiliacs in the case of recalls or the dissemination of information about product changes or changes in treatment.

724. The CHS received thousands of dollars in grants from companies such as Honeywell, Safeway and other companies.¹³³³ Moreover, the major fractionators, specifically Connaught, Cutter and Travenol donated large sums of money to the registry project.¹³³⁴ A number of staff were hired specifically to work on this project.¹³³⁵ From 1981 to 1982 over

Evidence of Anne Harrington, St. Michael's Hospital, Hemophilia Program, pp. 72-73; and

Evidence of Ed Kubit, CHS Manitoba Centre, p. 34594.

¹³³¹ Ex. 28, Vol. 11, p. 2173 (March, 1984, Hemophilia Today).

¹³³² Evidence of Ed. Kubit, CHS, Manitoba Centre, p. 34594.

¹³³³ Ex. 28, Vol. 11, p. 2168 (November, 1983, Hemophilia Today).

¹³³⁴ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32879-32881.

¹³³⁵ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32876-32878;

Ex. 75, Vol. 159, Part I, Tab 1 (January, 1983, Hemophilia Today); and

Ex. 28, Vol. 11, p. 2173 (March, 1984, Hemophilia Today).

\$600,000 was spent by the CHS on the hemophilia registry.¹³³⁶ Unfortunately, despite its efforts, the CHS national registry never materialized.

7) Product Distribution

725. The comprehensive care system is of particular benefit and importance when patients participate in a homecare/self-infusion programme. A centralized information system requires all registered hemophiliacs to keep treatment diaries. In turn, by monitoring treatment diaries, inappropriate use of blood products could be identified and corrected by the hemophiliac's physician. In addition, comprehensive care systems with a national registry would also allow for a quick and efficient recall of blood products from the homes of hemophiliacs at any time.¹³³⁷

726. During the 1970's and 1980's the comprehensive care centre system for hemophiliacs was developed. These clinics allowed hemophiliacs to be regularly treated in a single faculty by those who had expertise specifically in all aspects of hemophilia care. Such centres ensured accountability for product use. The clinics contained such specialists as a nurse, psychologist, orthopedic specialist, physiotherapist, and social worker. The first comprehensive

¹³³⁶ Evidence of Ed Gurney, former Executive Director of CHS, pp. 32886-32887;

Ex. 821 (Canadian Hemophilia Society Expenditures on Information System Period: 1981 - 1988).

¹³³⁷ Ex. 766, Vol. 172, Tab 32 (Position paper, A Proposal for Optimal Transfusion Practice for the Ontario Hemophiliac, June 1986);

Ex. 771, Vol. 177, Tab 23 (Minutes of Meeting of Ad Hoc Group of Canadian Hemophilia Centre Directors, dated February 10, 1988);

Ex. 756, Vol. 162, Tab 58 (Memo from Dr. Inwood to Dr. Herst, dated April 3, 1984);

Ex. 756, Vol. 162, Tab 59 (Draft Record of Decisions of CBC Advisory Sub-Committee, dated April 11, 1984, p. 6); and

Ex. 764, Vol. 160, Tab 15 (Agenda and Minutes of the CHS MSAC Meeting held on May 13, 1983, and CHS MSAC Proposed Terms of Reference).

care clinics were created in the province of Quebec in the late 1970's. Two were organized in Montreal, one in Quebec City and one in Sherbrooke. All hemophiliacs had to be registered with a centre to receive treatment. Such centres allowed it to be determined, for the first time, the number of hemophiliacs, the severity of their condition, the type of treatment, and the amount of product being utilized. This system was unique to the province of Quebec and did not exist elsewhere in Canada.¹³³⁸

727. Other provinces had comprehensive care facilities but hemophiliacs were not required to be registered to obtain treatment. There are now other additional centres including those in Toronto, London, Hamilton, Ottawa, Thunder Bay,¹³³⁹ Vancouver,¹³⁴⁰ St.

¹³³⁸ Evidence of Dr. Strawzynski, former MSAC Chair, pp. 31069-31076; and
Evidence of Ed Kubin, CHS Manitoba Chapter, p. 34590.

¹³³⁹ Evidence of Anne Harrington, Hemophilia Nurse, July 14, 1995;
Evidence of Dr. Teitel, Hemophilia Treater, p. 33771;
Evidence of Dr. Inwood, Hemophilia Treater, pp. 33303-33305;
Evidence of Dr. Walker, Hemophilia Treater, pp. 33307-33308;
Evidence of Dr. Macauley, Chief of Pathology at Hotel Dieu Hospital and Cornwall General Hospital, p. 25898; and
Evidence of Michael Conflitte, Hemophiliac, p. 1753

¹³⁴⁰ Evidence of Lois Lindner, Hemophilia Nurse, July 14, 1995.

John's,¹³⁴¹ Saskatoon¹³⁴², Winnipeg¹³⁴³, Edmonton, Calgary,¹³⁴⁴ Moncton,¹³⁴⁵ and Charlottetown.¹³⁴⁶

728. Without comprehensive care, product-tracking is dependent on the record-keeping practices of hemophilia clinics and hospital blood banks. Hemophiliacs received blood products from hospitals without being required to follow up or account for their product use.¹³⁴⁷ There were instances of hemophiliacs who were obtaining and infusing concentrates without proper supervision from their attending physicians. This was recognized as the responsibility of the prescribing physician.¹³⁴⁸

729. As stated previously, the CRCS medical directors had no role in overseeing or determining the treatments used by hemophiliacs nor were they regularly consulted in a physician's deliberation of whether or not to perform a transfusion.¹³⁴⁹ Winnipeg was the only BTS Centre where concentrates or cryoprecipitate was directly distributed to patients. Problems with lack of product accountability frustrated Winnipeg's BTS personnel and was recognized by

¹³⁴¹ Evidence of Joy Bartlett, Hemophilia Nurse, July 14, 1995.

¹³⁴² Evidence of Carol Bell, Hemophilia Nurse, July 14, 1995.

¹³⁴³ Evidence of Ed Kubin, CHS Manitoba Chapter, p. 34591.

¹³⁴⁴ Evidence of Dr. Poon, Hemophilia Treater, pp. 34381-34382; and

Evidence of Dr. Turner, Edmonton Centre Medical Director, p. 7319.

¹³⁴⁵ Evidence of Mr. Thompkins, CHS Panel, p. 11437.

¹³⁴⁶ Evidence of Dr. Ross, P.E.I. Medical Director, pp. 13504-13505.

¹³⁴⁷ Ex. 765, Vol. 171, Tab 1 (1985 Position Paper on "Comprehensive Care in Ontario"); and

Ex. 766, Vol. 172, Tab 32, p. 161 (June 1986 Position Paper by Dr. Martin Inwood called "Optimal Transfusion Practice for Ontario Hemophiliacs").

¹³⁴⁸ Evidence of Dr. Inwood, Hemophilia Treater, pp. 33402-33404.

¹³⁴⁹ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20597, 21340-21342; and

Ex. 539, Tab 1, pp. 30-31 (Clinical Guide to Transfusion).

hemophilia treaters themselves. Dr. Rayner, a Winnipeg clinic treater, reminded Nora Schwetz, the Hemophilia Program Nurse Co-ordinator:

The Red Cross releases concentrates directly to hemophiliacs on home care, and we infer that this material has been prescribed by the responsible physician. However, it is not up to the staff at Red Cross to police the use of concentrate by your patients.¹³⁵⁰

730. Without a mandated comprehensive care system and patient registry, the CRCS was not in a position to ensure that there was an accurate paper trail to record which patients had received which concentrates. CRCS staff distributed blood components and plasma derivatives to hospitals and comprehensive care clinics, as requested, in accordance with the treaters' or hospitals' treatment protocols.¹³⁵¹ As Dr. Rayner reminded Ms. Schwez in his memo:

...if, whenever you wish to limit the amount of material available to an individual patient, the responsible physician would write to me or Dr. Schroeder, placing a limit on the amount of concentrate, which is being prescribed. If the patient wished more, we will recommend that he discuss this with his own physician.¹³⁵²

8) Formal Relationship between CRCS and CHS MSAC

731. Prior to the addition of a BTS representative on the CHS MSAC in late 1983, there was no formal link between the CRCS and the CHS MSAC. However, there were numerous channels of communication and informal links between the two groups. As outlined earlier, the CHS and CHS MSAC, played an advocacy and advisory role on behalf of Canadian hemophiliacs. Members were in regular contact with other parties in the Canadian blood

¹³⁵⁰ Ex. 763, Vol. 169, Tab 58 (*Memo to Nova Schwetz from Dr. Rayner, dated August 20, 1985*).

¹³⁵¹ Ex. 766, Vol. 172, Tab 32, p. 161 (*June 1986, Position Paper by Dr. Martin Inwood called "Optimal Transfusion Practice for Ontario Hemophiliacs"*).

¹³⁵² Ex. 763, Vol. 169, Tab 58 (*August 20, 1985, Memo to Nova Schwetz from Dr. Rayner*).

system, including the CRCS, the Federal and Provincial governments and the CBC.¹³⁵³ Some CRCS Medical Directors and Deputy Medical Directors were members of the national or local chapters of the CHS MSAC (in particular, Drs. Herst, Poon, Ross and McSheffrey). This network enabled frequent communication between parties in the blood system and facilitated a smooth exchange of information between the organizations.

732. By way of example, prior to and throughout 1983, the CRCS initiated communications with the CHS on many issues relevant to the treatment of hemophilia and the Canadian blood system. Some examples¹³⁵⁴ follow:

- In 1978 Dr. Derrick recognized the importance of having an MSAC member included in any discussions about distribution of AHF. He provided the local centre directors with a list of each of the CHS MSAC contacts in order to facilitate discussions between CRCS and hemophilia treaters about equitable concentrate distribution.¹³⁵⁵
- Dr. Derrick and Dr. Strawczynski co-chaired the afternoon session of the February 7, 1983 CHS MSAC/CRCS meeting on AIDS. (At the closed morning session, the MSAC had met without the CRCS and had drafted "Recommendations for the Treatment of Hemophiliacs", in response to some reports of hemophiliacs developing AIDS.)¹³⁵⁶
- On March 21, 1983 Dr. Naylor provided Ed Gurney (Executive Director of the CHS), with information on the sources of the 1983 supply of Factor VIII concentrate. He also

¹³⁵³ Evidence of Dr. Card, former MSAC Chair, pp. 31527-31528.

¹³⁵⁴ NOTE: Many of these examples are more fully discussed in context elsewhere in this document.

¹³⁵⁵ Ex. 750, Vol. 157, Tab 24 (Memo from Dr. Derrick to all Medical Directors and Technical Supervisors re: AHF Concentrate: Distribution and Utilization, dated December 12, 1978).

¹³⁵⁶ Ex. 762, Vol. 159, Part I, Tab 36 (Minutes of CHS MSAC/CRC BTS Meeting on AIDS, dated February 7, 1983); and

Ex. 762, Vol. 159, Part I, Tab 37 (Memo to file from Drs. Naylor and Derrick re: CHS/CRC BTS Meeting on AIDS, dated February 9, 1983).

reminded Mr. Gurney of the information the CRCS required to ensure that an adequate supply of Factor VIII was ordered. The CRCS required statistics on the number of patients with hemophilia A, B and Von Willebrand Disease; the severity of their condition, age and regional distribution; information on other patients with other coagulation disorders; and utilization statistics.¹³⁵⁷

- At the May 1983 meeting of the CHS MSAC, Drs. Naylor and Davey made a presentation on the availability and source of the 1983 AHF concentrate supply.¹³⁵⁸
- On May 17, 1983, Dr. Naylor wrote to Dr. Strawczynski, to request an up-to-date census of Canadian hemophiliac with product utilization statistics.¹³⁵⁹
- In June 1983 Dr. Naylor sent Bill Mindell, information on the 1982 supply of concentrates including utilization notes and projections on future availability. Mr. Mindell was told that 50% of concentrates were prepared from commercial plasma.¹³⁶⁰
- On August 10, 1983, Dr. Naylor and Dr. Strawczynski discussed the geographic distribution of concentrates prepared from Red Cross plasma versus those prepared from commercial plasma.¹³⁶¹

¹³⁵⁷ Ex. 753, Vol. 159, Part II, Tab 18 (Letter from Dr. Naylor to Mr. Gurney re: 1983 Requirements of Factor VIII Source of Product, dated March 21, 1983).

¹³⁵⁸ Ex. 754, Vol. 160, Tab 15 (Agenda and Minutes of the CHS MSAC Meeting held on May 13, 1983, and CHS MSAC Proposed Terms of Reference).

¹³⁵⁹ Ex. 754, Vol. 160, Tab 22 (Letter from Dr. Naylor to Dr. Strawczynski re: 1982 Statistics on Coagulation Product Utilization at Montreal Children's Hospital, dated May 17, 1983).

¹³⁶⁰ Ex. 764, Vol. 160, Tab 35 (Letter from Dr. Naylor to Dr. Mindell re: Information on Donor Acceptance Criteria, Laboratory Testing of Donor Blood, Donor Deferrals and Factor VIII Concentrate from Commercial Sources, dated June 7, 1983).

¹³⁶¹ Ex. 754, Vol. 160, Tab 63 (Memo to file by Dr. Naylor re: August 10 Telephone Conversation with Dr. Strawczynski, dated August 15, 1983).

- On August 24, 1983, Dr. Naylor contacted Ed Gurney concerning a withdrawal of a potentially hepatitis-infected lot of commercial Factor VIII.¹³⁶²
- On August 26, 1983, Dr. Naylor wrote to Dr. Strawczynski concerning the sources of concentrates.¹³⁶³
- On September 1, 1983, Dr. Naylor spoke with Ed Gurney concerning the recall of AmCross source Hyland concentrate.¹³⁶⁴
- September 7, 1983, Dr. Davey notified the CHS that the supplementary contract with CLL had been cancelled due to the two recalls of CLL concentrate.¹³⁶⁵
- On September 7, 1983, Dr. Davey wrote to Dr. Strawczynski with further information on the cancellation of the Connaught contract.¹³⁶⁶
- On September 7, 1983, Dr. Naylor met with Joanne Harper, Executive Vice-President of the Ontario Chapter of the CHS, to discuss ways to improve communication between the CRCS treating physicians, and hemophiliacs.¹³⁶⁷

¹³⁶² Ex. 754, Vol. 160, Tab 72 (*Memo to file by Dr. Naylor re: August 24 Telephone Conversation with Mr Gurney of CHS, dated August 25, 1983*).

¹³⁶³ Ex. 754, Vol. 160, Tab 73 (*Letter from Dr. Naylor to Dr. Strawczynski re: Distribution of Factor VIII Concentrate in Canada, dated August 26, 1983*).

¹³⁶⁴ Ex. 755, Vol. 161, Tab 4 (*Memo to file by Dr. Naylor, dated September 2, 1983*).

¹³⁶⁵ Ex. 755, Vol. 161, Tab 10 (*Letter from Dr. Davey to Mr. Gurney re: Connaught Supplementary Supply of AHF Concentrate, dated September 7, 1983*).

¹³⁶⁶ Ex. 755, Vol. 161, Tab 11 (*Letter from Dr. Davey to Dr. Strawczynski re: Recall of Connaught AHF and Cancellation of Further Supplementary Purchases, 1983, dated September 7, 1983*).

¹³⁶⁷ Ex. 755, Vol. 161, Tab 15 (*Memo to file by Dr. Naylor re: Visit by Executive Vice President, Ontario Chapter of the CHS, dated September 8, 1983*).

- On September 29, 1983, Dr. Naylor, Bill Rudd and Ken Poyer met to discuss CRCS and CHS co-operation and the concentrate supply in general.¹³⁶⁸
- On October 6, 1983, Dr. Davey wrote to Dr. Strawczynski to advise her that Hyland stock would replace CLL stock. He also advised her of complaints about the recall process. The CRCS had promptly notified hospitals but there was a communication breakdown between hospitals and hemophiliacs.¹³⁶⁹
- On November 7, 1983, Dr. Naylor wrote to Dr. Strawczynski concerning recalled American Cutter lots.¹³⁷⁰ The letter was copied to Joanne Harper and Ed Gurney.
- In December 1983 the Ontario Fractionator Supplier User Group was struck to facilitate cooperation among producers, suppliers and AHF. Members included Drs. Blajchman, Davey, Garvey, Herst, Inwood, Naylor, Mercer and Rock.¹³⁷¹
- On December 15, 1983, Dr. Naylor replied to Dr. Strawczynski regarding the CHS request that FEIBA, concentrate for an inhibitor patients be distributed. This issue was to be discussed at length at an upcoming "inhibitor symposium".¹³⁷²

¹³⁶⁸ Ex. 755, Vol. 161, Tab 44 (Letter from Mr. Gurney to Dr. Naylor, dated October 13, 1983).

¹³⁶⁹ Ex. 755, Vol. 161, Tab 41 (Letter from Dr. Davey to Dr. Strawczynski re: Update on AIDS, dated October 6, 1983).

¹³⁷⁰ Ex. 755, Vol. 161, Tab 59 (Letter from Dr. Naylor to Dr. Strawczynski re: Recall of Cutter Factor VIII Concentrate (Koate), dated November 7, 1983).

¹³⁷¹ Ex. 755, Vol. 161, Tab 81 (Minutes of Meeting of the Ontario FSU Group, dated December 15, 1983).

¹³⁷² Ex. 755, Vol. 161, Tab 78 (Letter from Dr. Naylor to Dr. Strawczynski re: CHS Request that the National BTS Distribute FEIBA, dated December 15, 1983).

- On December 15, 1983, Dr. Naylor wrote to Ken Poyer summarizing the strategy for Factor VIII self-sufficiency and again requested an up-to-date census of hemophiliacs. The letter is copied to Ed Gurney, Bill Rudd and Dr. Strawczynski.¹³⁷³

9) CRCS Representation on CHS MSAC

733. The CRCS took the initiative to formalize ties to better facilitate communication between hemophilia treaters, hemophiliacs and the CRCS. On May 13, 1983, Drs. Naylor and Davey were invited to attend the CHS MSAC meeting to review figures on Factor VIII distribution at which time, Dr. Naylor asked that closer lines of communication be established between the CRCS and the CHS.¹³⁷⁴ On May 17, 1983 Dr. Naylor followed up his suggestion in a letter to Dr. Strawczynski, MSAC Chair:

...the potential impact of AIDS on modes of hemophilia treatment and consequently on utilization of coagulation products make the exchange of information between our organizations particularly important at this time so that we may respond to these situations in a cooperative way.¹³⁷⁵

734. MSAC, lay CHS members and the CRCS staff all felt that communication between the CHS and the CRCS could be improved. In September 1983, Dr. Strawczynski wrote to MSAC members to suggest that a CRCS consultant join the MSAC in order to facilitate mutual understanding and "solve many problems".¹³⁷⁶ As the CRCS was not the producer of plasma products, but merely a distributor, she believed that the CRCS played a politically neutral

¹³⁷³ Ex. 755, Vol. 161, Tab 79 (*Letter from Dr. Naylor to Mr. Poyer re: Approaches to Achieving Self-Sufficiency in Factor VIII Concentrate, dated December 15, 1983*).

¹³⁷⁴ Ex. 754, Vol. 160, Tab 16 (*May 13, 1983 Minutes of the Ontario Chapter MSAC Meeting*).

¹³⁷⁵ Ex. 754, Vol. 160, Tab 22 (*Letter from Dr. Naylor to Dr. Strawczynski re: 1982 Statistics on Coagulation Product Utilization at Montreal Children's Hospital, dated May 17, 1983*).

¹³⁷⁶ Evidence of Dr. Hanna Strawczynski, *Montreal Children's Hospital*, pp. 31496-31497.

role. Dr. Naylor was suggested as a candidate.¹³⁷⁷ As the response to Dr. Strawczynski's suggestion was favourable,¹³⁷⁸ Dr. Naylor's appointment to the CHS MSAC was confirmed by Dr. Strawczynski on April 2, 1984.¹³⁷⁹

735. Thereafter Dr. Naylor consulted with CHS members and hemophilia treaters. His role as an MSAC member enabled him to discuss with hemophilia treaters of changes which could be of "importance to the consumers", such as new fractionation contracts and the characteristics of different suppliers products. These formal connections between the CRCS and the CHS facilitated a quick and efficient exchange of information between the two organizations. It also ensured that the CHS had input into decisions made by the CRCS, which impacted on hemophilia treatment.¹³⁸⁰

736. Hemophilia treaters were advised of the CRCS purchasing policies and could monitor contracts and participate to an extent in CRCS decision making. In turn, a representative of the hemophilia treaters, Dr. Rivard, sat on the CRCS BTS Advisory Committee. The CRCS assumed that Dr. Rivard would keep both the treaters and CHS lay members informed about CRCS matters. As a member of the BTS Advisory Committee from November 1984 to November 1988, Dr. Rivard kept abreast of major scientific developments in transfusion medicine and was a party to decisions which had an impact on hemophilia treatment. Issues considered during his tenure included:

- CDC data on the efficacy of heat-treatment in disabling the HIV virus;¹³⁸¹

¹³⁷⁷ Ex. 755, Vol. 161, Tab 1 (*Memo from Dr. Strawczynski to all MSAC members, dated September 1983*).

¹³⁷⁸ Ex. 755, Vol. 161, Tab 13 (*Letter from Dr. Ali to Dr. Strawczynski, dated September 8, 1983*).

¹³⁷⁹ Ex. 756, Vol. 162, Tab 55 (*Report of the Chairperson of MSAC, dated April 2, 1984; and Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31083-31084*).

¹³⁸⁰ Ex. 755, Vol. 161, Tab 84 (*Letter from Dr. Strawczynski to Dr. Naylor, dated December 23, 1983*).

¹³⁸¹ Ex. 629, CRC Vol. 26, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting of November 2, 1984*).

- The status of fractionation contracts and updates on fulfilment of those contracts;¹³⁸²
- Availability of heat-treated concentrate and the status of the plan to introduce heat-treated AHF;¹³⁸³
- The Canadian concentrate supply including plasma source breakdown and availability;¹³⁸⁴
- The of implementation of HIV antibody testing and the results of testing trials;¹³⁸⁵
- CRCS lookback/traceback and donor notification procedures.¹³⁸⁶

¹³⁸² Ex. 629, CRC Vol. 26, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting, dated November 2, 1984*);

Ex. 634, CRC Vol. 31, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting of April 26, 1985*);

Ex. 644, CRC Vol. 41, Tab 22 (*Minutes of CRCS BTS Advisory Committee Meeting, dated April 18, 1986*);

Ex. 647, CRC Vol. 44, Tab 18 (*Minutes of CRCS BTS Advisory Committee Meeting, dated November 7, 1986*); and

Ex. 653, CRC Vol. 50, Tab 20 (*Journal Article: American Association of Blood Banks - Hepatitis Non-A, Non-B Virus Discovered, dated May 13, 1988*).

¹³⁸³ Ex. 634, CRC Vol. 31, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting of April 26, 1985*).

¹³⁸⁴ Ex. 634, CRC Vol. 31, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting of April 26, 1985*);

Ex. 649, CRC Vol. 46, Tab 12 (*Minutes of CRCS BTS Advisory Committee Meeting of June 12, 1987*); and

Ex. 654, CRC Vol. 51, Tab 20 (*Minutes of CRCS BTS Advisory Committee Meeting of November 14, 1988*).

¹³⁸⁵ Ex. 634, CRC Vol. 31, Tab 27 (*Minutes of CRCS BTS Advisory Committee Meeting of April 26, 1985*); and

Ex. 647, CRC Vol. 44, Tab 18 (*Minutes of CRCS BTS Advisory Committee Meeting of November 7, 1986*).

¹³⁸⁶ Ex. 644, CRC Vol. 41, Tab 22 (*Minutes of CRCS BTS Advisory Committee Meeting of April 18, 1986*);

Ex. 649, CRC Vol. 46, Tab 12 (*Minutes of CRCS BTS Advisory Committee Meeting of June 12, 1987*);

Ex. 651, CRC Vol. 48, Tab 11 (*Minutes of CRCS Blood Services Advisory Committee Meeting of November 27, 1987*); and

Ex. 653, CRC Vol. 50, Tab 13 (*Minutes of CRCS National Blood Services Committee Meeting of April 25, 1988*).

- The status of surrogate testing for NANB hepatitis;¹³⁸⁷
- Concentrate recalls;¹³⁸⁸
- Reports on methods of viral inactivation and the supply of enhanced viral inactivated Factor VIII.¹³⁸⁹

737. During the time leading up to the introduction and the transition to heat-treated concentrate in Canada, the CRCS was in communication with members of the CHS on a regular and ongoing basis¹³⁹⁰:

- September 15, 1984: Drs. Naylor and Derrick met with Drs. Card, Poon and Barnard, hemophilia treaters census of Canadian information on hemophiliacs.¹³⁹¹

¹³⁸⁷ Ex. 644, CRC Vol. 41, Tab 22 (Minutes of CRCS BTS Advisory Committee Meeting of April 18, 1986);

Ex. 647, CRC Vol. 44, Tab 18 (Minutes of CRCS BTS Advisory Committee Meeting of November 7, 1986);

Ex. 649, CRC Vol. 46, Tab 22 (Minutes of CRCS BTS Advisory Committee Meeting of June 12, 1987);

Ex. 651, CRC Vol. 48, Tab 11 (Minutes of CRCS Blood Services Advisory Committee of November 27, 1987);

Ex. 653, CRC Vol. 50, Tab 13 (Minutes of CRCS National Blood Services Committee Meeting of April 25, 1988); and

Ex. 654, CRC Vol. 51, Tab 20 (Minutes of CRCS National Blood Services Committee Meeting of November 14, 1988).

¹³⁸⁸ Ex. 651, CRC Vol. 48, Tab 11 (Minutes of CRCS Blood Services Advisory Committee of November 27, 1987).

¹³⁸⁹ Ex. 651, CRC Vol. 48, Tab 11 (Minutes of CRCS Blood Services Advisory Committee of November 27, 1987); and

Ex. 653, CRC Vol. 50, Tab 13 (Minutes of CRCS National Blood Services Committee Meeting of April 25, 1988).

¹³⁹⁰ A complete discussion on Heat Treatment can be found in Section III F of this submission.

¹³⁹¹ Ex. 758, Vol. 164, Tab 18 (Memo to File by D.H. Naylor, dated October 1, 1984).

- September 28, 1984: Dr. Naylor sent a copy of the CRCS Hemophilia Ontario article on heat-treated concentrates, to Dr. Card, Bill Rudd, a past President, and Ed Gurney of the CHS.¹³⁹²
- October 9, 1984: Dr. Naylor and Bill Rudd discussed the CRCS action with regard to the Coroner's recommendations Milito Artibano inquest.¹³⁹³
- October 11, 1984: Dr. Naylor, Craig Anhorn and Bill Mindell met concerning the 1984 shortages of concentrate.¹³⁹⁴
- October 19, 1984: Dr. Naylor and Dr. Derrick met with the CHS Blood Resources Committee to discuss the Factor VIII concentrates supply, a concentrate reporting system, and the Milito Coroner's Inquest.¹³⁹⁵
- October 27, 1984: Dr. Naylor and Dr. Card discussed the NHF recommendation to concerning heat-treated concentrates.¹³⁹⁶
- November 13, 1984: Dr. Perrault wrote to Bill Rudd to confirm that an inventory of three months supply of concentrate was advocated by CBC Advisory Committee. Dr. Perrault also reported on heat treated Factor VIII. The CHS now had a representative on the BTS Advisory Sub-Committee through Dr. Rivard. The letter was copied to a number of CHS and CHS MSAC members.¹³⁹⁷

¹³⁹² Ex. 758, Vol. 164, Tab 14 (*Letter to Dr. Card from Dr. Naylor, September 28, 1984*).

¹³⁹³ Ex. 758, Vol. 164, Tab 20 (*Memo to File by D.H. Naylor, dated October 10, 1984*).

¹³⁹⁴ Ex. 758, Vol. 164, Tab 24 (*Memo to file by Bill Mindell, dated October 11, 1984*).

¹³⁹⁵ Ex. 758, Vol. 164, Tab 30 (*Summary of Meeting between CHS and CRC National BTS Representatives, dated October 19, 1984*).

¹³⁹⁶ Ex. 758, Vol. 164, Tab 36 (*Memo to file by Dr. Naylor, dated October 29, 1984*).

¹³⁹⁷ Ex. 759, Vol. 165, Tab 12 (*Letter from Dr. Perrault to Bill Rudd, dated November 13, 1984*).

- November 15, 1984: Dr. Naylor responded to complaints about CLL concentrates. The letter to Bill Mindell was copied to Dr. Irwin Walker and hemophiliacs Bill Rudd and Dan Huneault.¹³⁹⁸
- November 26, 1984: Dr. Naylor wrote to Dr. Growe and informed him about the Consensus Conference to be held on the introduction of heat-treated concentrates. ~
- November 28, 1984: Dr. Naylor and Bill Mindell discussed the CBC Consensus Conference, CLL concentrates, Fractionator/ Supplier/ User Group representation and the manufacture of cryoprecipitate from female donors.¹³⁹⁹
- December 4, 1984: Dr. Naylor and Dr. Card discussed the Consensus Conference and heat-treated concentrates.¹⁴⁰⁰
- December 20, 1984: The CRCS and CHS issued a Joint Statement on the Consensus Conference and the introduction of heat-treated concentrates.¹⁴⁰²
- January 8, 1985: The Ontario Fractionator/ Supplier/ User Group met to discuss the introduction of heat-treated concentrates and the transition period criteria. Hemophilia treaters attended including Drs. Walker, Inwood and Garvey.¹⁴⁰³

¹³⁹⁸ Ex. 759, Ex. 165, Tab 14 (*Letter from Dr. Naylor to Bill Mindell, dated November 15, 1984*).

¹³⁹⁹ Ex. 759, Vol. 165, Tab 26 (*Letter from Dr. Naylor to Dr. Growe, dated November 26, 1984*).

¹⁴⁰⁰ Ex. 759, Vol. 165, Tab 31 (*Memo to file by Dr. Naylor, dated November 28, 1984*).

¹⁴⁰¹ Ex. 759, Vol. 165, Tab 44 (*Memo to file by Dr. Naylor, dated December 6, 1984*).

¹⁴⁰² Ex. 759, Vol. 165, Tab 67 (*Press Release: Joint Canadian Red Cross/Hemophilia Society Statement re Provision of heat-treated coagulation factors in Canada, dated December 20, 1984*).

¹⁴⁰³ Ex. 760, Vol. 166, Tab 4 (*Minutes of the Ontario FSU Group Meeting, dated January 8, 1985*).

- January 14, 1985: Dr. Naylor wrote to Dr. Card concerning concentrate packaging. The CRCS was attempting to determine their estimate for heat-treated concentrates introduction and stated that they would inform the MSAC of the firm date when known.¹⁴⁰⁴
- January 14, 1985: Dr. Naylor wrote to Dr. Walker concerning clinical trials of heat-treated concentrates. Dr. Walker was informed that deliveries of Cutter heat-treated commercial or CRCS concentrates would "be unlikely before the end of April."¹⁴⁰⁵
- January 29, 1985: Dr. Naylor wrote to Dr. Walker to request information on the number of hemophiliacs and average utilization for use in supply planning.¹⁴⁰⁶
- February 1, 1985: Dr. Naylor wrote to Bill Mindell, with respect to user complaints about CLL concentrates.¹⁴⁰⁷
- February 14, 1985: Dr. Naylor provided Drs. Card and Walker with a draft recall plan.^{1408 1409}
- February 20, 1985: Dr. Naylor wrote to Dr. Walker to remind him to send comments on the recall draft.¹⁴¹⁰

¹⁴⁰⁴ Ex. 760, Vol. 166, Tab 8 (*Letter from Dr. Naylor to Dr. Card, dated January 14, 1985*).

¹⁴⁰⁵ Ex. 760, Vol. 166, Tab 9 (*Letter from Dr. Naylor to Dr. Walker, dated January 14, 1985*).

¹⁴⁰⁶ Ex. 760, Vol. 166, Tab 16 (*Letter from Dr. Naylor to Dr. Walker, dated January 29, 1985*).

¹⁴⁰⁷ Ex. 760, Vol. 166, Tab 19 (*Letter from Dr. Naylor to Bill Mindell, dated February 1, 1985*).

¹⁴⁰⁸ Ex. 760, Vol. 166, Tab 37 (*Letter from Dr. Naylor to Dr. Card, dated February 14, 1985*).

¹⁴⁰⁹ Ex. 760, Vol. 166, Tab 38 (*Letter from Dr. Naylor to Dr. Walker, dated February 14, 1985*).

¹⁴¹⁰ Ex. 760, Vol. 166, Tab 41 (*Letter from Dr. Naylor to Dr. Walker, dated February 20, 1985*).

- March 15, 1985: Dr. Naylor replied to Ed Gurney with respect to the CHS Blood Products Policy.¹⁴¹¹ ¹⁴¹²
- March 23, 1985: Dr. Naylor attended the Ontario CHS MSAC meeting and informed the hemophilia treaters that heat-treated concentrates would be distributed, commencing May 1.¹⁴¹³
- April 19, 1985: Dr. Naylor attended the national CHS MSAC meeting.¹⁴¹⁴
- April 25, 1985: Dr. Card sent the CHS MSAC priority list recommendations to Dr. Naylor. The letter and attachments were copied to Linda Laxdal, Ed Gurney, Bill Rudd of the CHS and all members of MSAC and hemophilia clinic directors.¹⁴¹⁵
- April 29, 1985: Dr. Naylor copied Dr. Card and Bill Rudd with a memo which outlined the plan for the distribution of heat-treated concentrates during the transition period.¹⁴¹⁶
- May 3, 1985: Dr. Naylor and Ed Gurney discussed the transition period criteria, AIDS and hemophilia; and the new CHS Blood Products Policy.¹⁴¹⁷

¹⁴¹¹ Ex. 761, Vol. 167, Tab 15 (Letter from Dr. Naylor to Ed Gurney, dated March 15, 1985).

¹⁴¹² Ex. 761, Vol. 167, Tab 17 (Memo from Dr. Naylor to BTS Centre Medical Directors, dated March 20, 1985).

¹⁴¹³ Ex. 761, Vol. 167, Tab 22 (Trip Report by Dr. Naylor to CHS MSAC Meeting, dated March 23, 1985).

¹⁴¹⁴ Ex. 761, Vol. 167, Tab 53 (Minutes of CHS MSAC Meeting, dated April 19, 1985); and

Ex. 761, Vol. 167, Tab 57 (Trip Report by Dr. Naylor to Annual Meeting of National CHS MSAC, dated April 19, 1985).

¹⁴¹⁵ Ex. 761, Vol. 167, Tab 65 (Letter from Dr. Card to Dr. Naylor, dated April 25, 1985).

¹⁴¹⁶ Ex. 761, Vol. 167, Tab 71 (Memo from Dr. Naylor to BTS Centre Medical Directors, dated April 29, 1985).

¹⁴¹⁷ Ex. 762, Vol. 168, Tab 4 (Memo from Dr. Herst to CRC BTS Laboratory Staff, dated May 2, 1985).

- May 27, 1985: Dr. Naylor sent Dr. Card and Dr. Walker a memo on the clinical trials of heat-treated concentrates.¹⁴¹⁸
- May 28, 1985: Dr. Naylor replied to Ed Gurney and Dr. Card with regard to the CHS Board of Directors recommendations.¹⁴¹⁹
- May 30, 1985: Dr. Naylor sent a memo on heat-treatment conversion to Dr. Card and all hemophilia clinic directors.¹⁴²⁰

10) Medical Directors/Treaters: Wearing of Two Hats

738. In Canada, relatively few physicians have expertise in haematology and coagulation. For this reason, at times, certain hemophilia treating physicians were employed on a part-time basis as deputies or part-time Medical Directors at the local CRCS Centres. Concern had been expressed that this constituted a conflict of interest and that these treaters might be influenced in their decisions concerning the treatment of hemophilia by their positions with the CRCS.¹⁴²¹

739. The expert panel of the Safety Audit Hearing saw no problem with such overlap. They testified that if good manufacturing practices and a good quality programme were in place, that a system would work well. Moreover, Ms. Robbins of the Safety Audit Panel testified that she thought it important that people who were involved in the blood system were exposed to the

¹⁴¹⁸ Ex. 762, Vol. 168, Tab 38 (*Memo from Dr. Naylor to Dr. Davey, dated May 27, 1985*).

¹⁴¹⁹ Ex. 762, Vol. 168, Tab 39 (*Letter from Dr. Perrault to Ed Gurney, dated May 28, 1985*).

¹⁴²⁰ Ex. 762, Vol. 168, Tab 45 (*Memo from Dr. Naylor to Medical Director and Technical Supervisor, dated May 30, 1985*).

¹⁴²¹ *Evidence of Dr. Kreppner, pp. 3977-3980.*

ultimate customer or patient via networking through the medical field.¹⁴²² She could not comment on whether the informality of communications was a drawback to the system. However, there were many avenues of communication in a blood system.¹⁴²³

740. Members of the National CHS MSAC were employed by the CRCS on an extremely limited basis and each of the positions had varying degrees of time commitments to the CRCS.¹⁴²⁴ In the case of Dr. Dorothea Barnard, MSAC representative from Nova Scotia, very little time was spent at the CRCS Centre, sometimes time commitments working out to two days a week and then no attendance for a month. Their schedule was usually determined by the full-time Medical Director depending upon the assistance required at the Centre.¹⁴²⁵ In some cases, MSAC physicians were brought into CRCS Centres to address specific problems and to provide advice on coagulation issues.¹⁴²⁶

741. Dr. Card testified that in his role as Deputy Medical Director at the Saskatoon BTS, he acted for the Medical Director when unavailable. Dr. Card was also involved in consultations and was required to be at the Centre several times a week when plasmapheresis donors attended, as a physician was required to be on site during this procedure.¹⁴²⁷

742. In the case of Dr. Ross, her ".2" position at the CRCS Centre on Prince Edward Island essentially meant that she covered for Dr. Craig, the Medical Director during the summer months.¹⁴²⁸

¹⁴²² Evidence of Jenny Lee Robbins, Safety Audit Panel, p. 20871.

¹⁴²³ Evidence of Jenny Lee Robbins, Safety Audit Panel, pp. 20872-20873.

¹⁴²⁴ Evidence of Dr. Perrault, former National Director BTS, p. 30223.

¹⁴²⁵ Evidence of Dr. Perrault, former National Director BTS, p. 30223.

¹⁴²⁶ Evidence of Dr. Perrault, former National Director BTS, p. 30223.

¹⁴²⁷ Evidence of Dr. Card, former MSAC Chair, pp. 31643-31644.

¹⁴²⁸ Evidence of Dr. Ross, Medical Director Charlottetown Centre, P.E.I., p. 13554.

743. Dr. Rayner, a hemophilia treater and Deputy Medical Director of the Winnipeg Centre from September, 1984 to April, 1988, would spend two mornings a week in an office at the CRCS Centre, where his duties included covering in the absence of the Medical Director. As in the case of Dr. Card, he was to be present on site to trouble shoot problems with blood donors or pheresis donors.¹⁴²⁹ Dr. Rayner, in total, spent approximately seven hours a week at the Winnipeg Centre.¹⁴³⁰

744. While Dr. Herst was a full-time CRCS employee at the same time she was a member of the CHS MSAC and Ontario MSAC, she was not an actual treater at this time. Nor, as a deputy Medical Director, was she in charge of the Centre.

745. The hemophilia treating physicians employed part-time by the CRCS testified that their positions with their respective organizations did not pose a conflict of interest.¹⁴³¹ Dr. Herst for example, found that the two positions were complimentary. Attendance at the MSAC meetings as well as participation at the CRCS gave them a chance to receive "customer input and exchange information very effectively", thereby providing a two-way exchange of information.¹⁴³² She testified:

CHERNIAK: From either one of your roles was there any pressure put on you, directly or indirectly, either from the Red Cross on the one hand or the hemophilia community on the other hand to slant your recommendations or work in one direction or another?

HERST: No pressure was put on me at all.

CHERNIAK: Do I understand you to think that there was some benefit in your joint roles?

¹⁴²⁹ Evidence of Dr. Rayner, Deputy Medical Director, Winnipeg Centre, p. 34152.

¹⁴³⁰ Evidence of Dr. Rayner, Deputy Medical Director, Winnipeg Centre, p. 34153.

¹⁴³¹ Evidence of Dr. Herst, Toronto Centre Medical Director, p. 34109; and

Evidence of Dr. Ross, Medical Director Charlottetown Centre, P.E.I., p. 32800.

¹⁴³² Evidence of Dr. Herst, Toronto Centre Medical Director, p. 21392.

HERST: Yes, I do think definitely that there was benefit.¹⁴³³

746. From the CRCS's perspective, members of MSAC employed by the CRCS were minor part-time employees, while other treaters, such as Dr. Rivard, fulfilled advisory roles only.¹⁴³⁴ Moreover, the only person in attendance at the National MSAC who directly represented CRCS's interest was Dr. Naylor.¹⁴³⁵ Dr. Naylor was requested to sit on MSAC as a CRCS consultant at the request of Dr. Strawczynski and with the full support of the other hemophiliac treaters.¹⁴³⁶

¹⁴³³ Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 21392-21393.

¹⁴³⁴ Evidence of Dr. Perrault, former National Director BTS, pp. 29456-29461.

¹⁴³⁵ Evidence of Dr. Perrault, former National Director BTS, p. 29461.

¹⁴³⁶ See CRCS/CHS MSAC Relations.

